

# EXHIBIT 38

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In Re:  
Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

All Actions MDL No.  
15-2666 (JNE/FLM)  
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VIDEOTAPED DEPOSITION

OF

MARK ALBRECHT

VOLUME 1

Minneapolis, Minnesota

Friday, October 7th, 2016  
-----

Reported by:  
Amy L. Larson, RPR  
Job No. 112502

## 1 APPEARANCES:

2 ON BEHALF OF 3M:

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23 ALSO PRESENT: Kraig Hildahl, Videographer

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1 ALBRECHT

2 THE VIDEOTAPED DEPOSITION OF MARK ALBRECHT,  
3 VOLUME 1, taken on this 7th day of October, 2016,  
4 at the Law Offices of Blackwell, Burke, LLP,  
5 431 South Seventh Street, Suite 2500, Minneapolis,  
6 Minnesota, commencing at approximately 9:17 a.m.

7  
8 P R O C E E D I N G S

9  
10 THE VIDEOGRAPHER: This is the  
11 start of tape labeled number 1 in the  
12 videotaped deposition of Mark Albrecht in the  
13 matter of In Re: Bair Hugger Forced Air  
14 Warming Products Liability Litigation, in the  
15 U.S. District Court, District of Minnesota.  
16 The MDL case number is 15-2666 (JNE/FLN).

17 This deposition is being held at  
18 Blackwell, Burke law firm in Minneapolis,  
19 Minnesota on October 7th, 2016. The time is  
20 9:18 a.m. My name is Kraig Hildahl, I'm a  
21 legal video specialist from TSG Reporting.  
22 The court reporter is Amy Larson also with  
23 TSG Reporting.

24 Will counsel please introduce  
25 themselves for the record.

1 ALBRECHT

2 MR. C. GORDON: Corey Gordon and  
3 Peter Goss on behalf of defendant 3M.

4 MR. B. GORDON: Ben Gordon for the  
5 plaintiffs.

6 MR. ASSAAD: Gabriel Assaad for  
7 the plaintiffs.

8 MS. ZIMMERMAN: Genevieve  
9 Zimmerman for the plaintiffs.

10 MR. PAREKH: Behram Parekh for  
11 plaintiffs.

12 THE VIDEOGRAPHER: Will the court  
13 reporter please swear in the witness and we  
14 can proceed.

15  
16 MARK ALBRECHT,  
17 a witness in the above-entitled action,  
18 after having been first duly sworn, was  
19 deposed and says as follows:

20  
21 EXAMINATION

22 BY MR. C. GORDON:

23 Q. Good morning, Mr. Albrecht.

24 A. Hello.

25 Q. To reintroduce myself, I'm Corey Gordon, and

1 ALBRECHT

2 I -- I represent 3M in a multi-district  
3 litigation involving claims over the 3M  
4 Bair Hugger warming device.

5 A. Uh-huh.

6 Q. I'm here to ask you questions about some of  
7 the work you -- you did in connection with  
8 that. First of all, let's -- have you ever  
9 had your deposition taken before?

10 A. No.

11 Q. Okay. Just some ground rules that will make  
12 everything smoother. You can see the court  
13 reporter is using the machine to take down  
14 everything I say, everything you say. Your  
15 testimony is sworn, it's as if you are in  
16 court. So you need to -- I need to wait  
17 until you're done with your answers, you need  
18 to wait until I'm done with my questions, in  
19 order for her to be able to transcribe what  
20 is being communicated. You need to give  
21 verbal answers, a yes or a no or whatever,  
22 rather than a uh-huh or huh-uh or a shake of  
23 the head that would ordinarily communicate if  
24 we were just talking to each other.

25 So it's -- there's a little --



1 ALBRECHT

2 A. I understand.

3 Q. -- a little bit of formality.

4 And it's just -- I can tell you,  
5 it's human nature to start an answer before a  
6 question is finished or start a question  
7 before an answer is finished. I'll try my  
8 best not to, and we may have to back up  
9 occasionally to make sure that only one  
10 person is talking at a time.

11 Because this is as if you are in  
12 court, there's no judge here, as you can see,  
13 but from time to time either side may make  
14 objections, if I ask a question and they make  
15 an objection, same thing when they ask you  
16 questions.

17 You're not represented by an  
18 attorney; is that correct?

19 A. Correct.

20 Q. So nobody -- nobody here is representing you,  
21 nobody here can instruct you not to answer a  
22 question, so objections are for the record.  
23 And even if there's an objection, go ahead  
24 and answer the question unless an objection  
25 is made and the asking attorney decides to

1 ALBRECHT

2 withdraw or -- or change the question. But  
3 just -- you know, it's an unusual procedure,  
4 I'm sure, for people who don't experience it  
5 regularly.

6 MR. B. GORDON: And if I could  
7 interject, Corey.

8 MR. C. GORDON: Sure.

9 MR. B. GORDON: Since this is your  
10 first time, Mark, there is an exception for  
11 privileged information, which is a legal  
12 issue, which we may or may not get into here.  
13 And if that happens, we'll talk about it.  
14 But if there's information that may be  
15 legally privileged that you don't have to  
16 answer then we may have to take that up with  
17 the court.

18 BY MR. C. GORDON:

19 Q. Let's start with your -- your background.

20 Where did you go to high school?

21 A. Chaska, Minnesota.

22 Q. When did you graduate?

23 A. 1998.

24 Q. And did you go on to post high school  
25 education right away?

1 ALBRECHT

2 A. Yeah, I went to Madison, Wisconsin.

3 Q. So how long were you a Cheesehead?

4 A. Never.

5 Q. Good answer.

6 A. But I was a Badger -- that's right, I was a  
7 Badger for four-and-a-half years, did a  
8 mechanical engineering degree.

9 Q. So you got that in 2002?

10 A. Give -- thereabouts. I think it was the  
11 January of '03, '02 flip-over, so...

12 Q. So that's a BSE?

13 A. Yeah, it's a bachelor of science.

14 Q. Are you -- did you ever become a professional  
15 engineer?

16 A. I did not.

17 Q. Okay. So after you got your mechanical  
18 engineering degree, did you go on for any  
19 additional postgraduate work?

20 A. I did later on in life. I started work  
21 first.

22 Q. Okay. Let's finish with the education and  
23 then we'll circle back --

24 A. Sure.

25 Q. -- to the work stuff.

1 ALBRECHT

2 What -- what postgraduate work have  
3 you done?

4 A. So I did an MBA at the University of  
5 Minnesota Carlson School of Management.

6 Q. When -- what period of time were you a  
7 student there?

8 A. That was probably '07 to 2010, thereabouts, I  
9 think. I'd have to look carefully. I think  
10 on the resume that I provided it would have  
11 the exact dates for that.

12 Q. Okay. So I just kind of want to get a quick  
13 overview. So you have -- you have an MBA  
14 from the U of M?

15 A. I do.

16 Q. Did that involve any kind of specialization?

17 A. Yeah, statistics specialization and market  
18 research. And I also have another graduate  
19 degree in statistics.

20 Q. And when did you get that?

21 A. Following the MBA. So it was kind of joint  
22 work with the two. So from 2010 on to 2012 I  
23 would say, I think it was, 2011, somewhere in  
24 there, 2012 to 2011, I completed my master's  
25 of statistics from the School of Statistics.

ALBRECHT

Q. At the U of M?

A. Yes.

Q. So now you're a Gopher?

A. Yeah, well, it's hard to cheer for anything,  
but -- sports are...

Q. Okay. So you have a master's of statistics,  
a master's of business administration --

A. I do.

Q. -- and a BS in mechanical engineering?

A. Yup.

Q. Any other degrees --

A. Nope.

Q. -- that I missed? Okay.

Let's go back now and sort of  
summarize your work history.

A. Uh-huh.

Q. Did you work while you were in college?

A. Just internships. So I had a couple at  
Arizant Healthcare, which you guys own. Not  
you, but 3M.

Q. 3M wouldn't have owned it at the time, right?

A. No, no.

Q. Okay. And so we'll -- we'll get some details  
on that. But then anything else that you did

1 ALBRECHT

2 while you were in college?

3 A. That relates to this, I don't know. I ran  
4 sailboat races during the summers, it was a  
5 part-time job too on Lake Minnetonka, had a  
6 one year internship at Entegris, which used  
7 to be Fluoroware, so that's like a  
8 semi-conductor company, and that was it.

9 Q. Okay. And then after you graduated from the  
10 University of Wisconsin what was your first  
11 full-time job?

12 A. It was as a research and development engineer  
13 at Arizant Healthcare.

14 Q. Was that essentially immediately after  
15 graduation?

16 A. Yeah.

17 Q. So starting in two thousand -- early -- early  
18 2003?

19 A. Yeah, that sounds right.

20 Q. And at that point was Scott Augustine still  
21 involved in the company?

22 A. Yeah.

23 Q. He was a CEO?

24 A. Yeah, he would have been.

25 Q. How long have you known Scott Augustine?

1 ALBRECHT

2 A. I only knew him from the internship on.

3 Q. How had you gotten connected with Arizant for  
4 the internship?

5 A. Sure. My dad was -- shared a dorm with him  
6 in college. And they weren't close or  
7 anything, he just saw this guy in the paper  
8 that he used to know and said hey, if you're  
9 looking for internships, why don't you throw  
10 a resume in there and see if you get an  
11 internship. So I was given a tour of the  
12 company by Scott, and that was about it for a  
13 while of seeing him.

14 Q. And your internship, was that in the research  
15 and development area?

16 A. Yes, it was.

17 Q. Okay. So you -- you started in 2003 as a  
18 full-time employee. What was your title?

19 A. Research and development engineer.

20 Q. Okay. And how long did you work in that  
21 capacity for Arizant?

22 A. It was two-and-a-half years probably. I'd  
23 have to figure out the exact dates. It was  
24 two to three years, somewhere in there.

25 Q. And was -- did Scott Augustine remain the CEO

1 ALBRECHT

2 the entire time you were there?

3 A. No.

4 Q. Approximately what time did Dr. Augustine  
5 leave Arizant?

6 A. It would have been a little over a year  
7 before I took off, so I was only there for  
8 maybe a year and a half while he was CEO,  
9 year, year and a half.

10 Q. And then how long were you there when -- how  
11 long were you part of Arizant when  
12 Dr. Augustine was no longer part of Arizant?

13 A. I think a little over a year, maybe a year  
14 and a half. So somewhere in the two- to  
15 three-year range all that stuff happened  
16 before I switched jobs and went to work for  
17 him.

18 Q. Okay. And you stayed at Arizant in the --  
19 after Dr. Augustine left in the same  
20 capacity?

21 A. Yup.

22 Q. Okay.

23 A. Yup.

24 Q. When you left Arizant, what was your next  
25 employment?



1 ALBRECHT

2 A. It was at Augustine Biomedical & Design, so  
3 that was with Scott Augustine.

4 Q. And how did it -- how did it come to pass  
5 that you went from Arizant to working for  
6 Augustine Biomedical?

7 A. I sought him out. He was recruiting  
8 engineers once his noncompete was up in terms  
9 of working with people from the company, so  
10 we had some discussions and it seemed like a  
11 fit.

12 Q. So when did you start at Augustine  
13 Biomedical?

14 A. I would have to look at dates on a resume if  
15 you have one. I think I provided one. But  
16 it would have been, I don't know, let's see  
17 here, 2002 -- '05, '06, somewhere in there, I  
18 believe.

19 Q. And what was your first position?

20 A. It was an engineer.

21 Q. In research and development?

22 MR. B. GORDON: And, Mark, you  
23 don't have to guess on things. If at any  
24 point you need to see a document to answer a  
25 question, just let us know.

1 ALBRECHT

2 THE WITNESS: Yeah, I think I  
3 provided a resume as part of the documents.  
4 Do you have that handy? Because I think it  
5 would be a lot easier for me to go through  
6 that way.

7 BY MR. C. GORDON:

8 Q. We can pull a copy. And I'm not looking for  
9 precision.

10 A. Okay.

11 Q. But I'll --

12 A. That's fine.

13 Q. But in fairness to you, when we take a break  
14 I'll get a copy it --

15 A. Okay.

16 Q. -- and you can make the record precise.  
17 But -- so I'm just now trying to get a  
18 general 50,000 foot overview.

19 So you worked in R&D at Augustine  
20 Biomedical for how -- roughly how long a  
21 period of time?

22 A. At Augustine Biomedical, I think two years,  
23 and I did a little bit of marketing product  
24 management for them for a while. That was  
25 still kind of -- it's a blended job. It's a

1 ALBRECHT

2 startup. You wear a lot of hats, right, and  
3 so I transitioned from an R&D engineer to a  
4 product marketer for a while as I was doing  
5 my MBA. And then as I got through the MBA  
6 and realized that the clinical research was a  
7 little more in line with what I wanted, I  
8 switched over and did their clinical research  
9 studies as I completed out my graduate degree  
10 in statistics. So it kind of lined up with  
11 where I was at in school how things went.

12 Q. So you were still an employee of Augustine  
13 Biomedical when you were attending the  
14 University of Minnesota?

15 A. Yes.

16 Q. For both the Carlson School of Business MBA  
17 and the master's of statistics?

18 A. Yes.

19 Q. And so when you were -- when you were at the  
20 U of M as a student, were you a full-time  
21 employee of Augustine Biomedical?

22 A. Three-quarter time. I was listed as  
23 full-time, but they were allowing me to  
24 attend school full-time, so you kind of do  
25 two jobs. It's life.

1 ALBRECHT

2 Q. Okay. And you were doing clinical research  
3 for Augustine Biomedical --

4 A. Yup.

5 Q. -- during that period of time?

6 A. I was. A blend of clinical and engineering  
7 research, we'll call it. It was kind of  
8 50/50 if you think about what's in the  
9 studies.

10 Q. When you first started Augustine Biomedical,  
11 what products, if any, were already  
12 developed?

13 A. There were a number of ideas that were  
14 thought of, but there wasn't a lot that was  
15 developed at that time.

16 Q. So you were essentially on the ground floor  
17 of the product development?

18 A. I was. I was not allowed to work on anything  
19 that was patient-warming related though for  
20 several years, because I had a noncompete  
21 with 3M. So I had worked on an allergy  
22 relief pillow for that period of time and  
23 also some catheterization-type ideas.

24 Q. Is this the pillow that has a --

25 A. Yeah.

ALBRECHT

Q. -- airflow of Hepa air over it?

A. Yeah, that's the one.

Q. Is that on the market?

A. You know, I don't think it ever got out.

Q. Okay.

A. It was kind of a pilot test and it never went.

Q. Dr. Gauthier mentioned it and --

A. Yeah, it's --

Q. -- I was kind of curious.

A. It was a great idea, but like a lot of great ideas, you know.

Q. So do you recall roughly what the period of your noncompete was with Arizant?

A. One year.

Q. Okay. So after that one year did you start working on any patient-warming devices?

A. It was longer than that. I was off on that allergy pillow piece not really doing much with the patient warming for several years.

Q. And what was your first involvement in -- in patient warming?

A. You know, it's hard to recall, but it was probably some stuff in the areas -- we were

1 ALBRECHT

2 using a heating fabric for a cannulization  
3 product that was related to patient warming,  
4 so I did some technology development with  
5 that, but it wasn't directly aimed at that.  
6 So that may have been the first thing that  
7 maybe crossed over, I don't know.

8 Q. Did there ever come a point in time when you  
9 did engineering research and development-type  
10 work as opposed to clinical research or  
11 marketing for HotDog, the HotDog product?

12 MR. B. GORDON: Object to the  
13 form.

14 THE WITNESS: No, I don't think I  
15 explicitly did that.

16 BY MR. C. GORDON:

17 Q. Did there ever come a point in time where you  
18 did any work of any kind in connection with  
19 the HotDog product?

20 A. Yeah. Yeah, the clinical research piece is  
21 directly related to that.

22 Q. Okay. And I guess what I'm -- obviously,  
23 we're going to talk about --

24 A. Sure.

25 Q. -- the clinical research for the bulk of

1 ALBRECHT

2 this, but I'm just trying to understand if  
3 you had any other work activities involving  
4 HotDog before you started doing clinical  
5 research?

6 A. You know, it's hard to exactly remember,  
7 because the blend-over was kind of gradual  
8 and we used some technologies in different  
9 products that related. So, yeah, there was a  
10 little bit, I'm sure, of engineering advice,  
11 guidance, design that happened on things that  
12 were put into the HotDog at some point.

13 Q. Let me --

14 A. If you have specifics I can --

15 Q. Well, I'm going to -- I'm going to -- I'm  
16 going to see if this helps narrow the time  
17 frame a little bit.

18 (Whereupon, Exhibit 1 was  
19 marked for identification.)

20 BY MR. C. GORDON:

21 Q. I'll show you what's been now marked as  
22 Albrecht Exhibit 1.

23 A. This is a clinical research document.

24 Q. Yeah. And -- and the reason I -- I -- I  
25 picked this one is because it's -- the date

ALBRECHT

on it is -- is September 14th, 2007, and that's the earliest document I've seen with your -- with your involvement --

A. Uh-huh.

Q. -- clear on its face, and I'm just -- and just looking at this I'm wondering if this -- this gives you any time frame as to yeah, okay, this is about when I would have started being involved in clinical research with the HotDog product or if there might have been stuff prior to this?

A. Yeah, maybe. I mean, the things with some of these documents, the dates on them too sometimes are off, because we use file reports that we just pull from other ones and put text in. So, like, I'm looking at the date on this and I'm thinking, you know, that might be right, '07, but it might have been a little bit later too. And so it's kind of ridiculous how that works, but you take a template and you smack stuff into it.

Q. Okay. And -- and Exhibit 1 is a report for -- from certain work -- research activities that were done at the



1 ALBRECHT

2 Regina Surgery Center --

3 A. Yup.

4 Q. -- in Hastings?

5 A. Yup.

6 Q. Do you recall doing work there?

7 A. Uh-huh. So that date --

8 Q. This is one of those examples you have to say  
9 yes or no.

10 A. Yes, I did do work there.

11 Q. It's -- it's stilted, and I apologize for it.

12 So -- and this is what I'm -- I  
13 guess what I hope seeing if it jogs your  
14 memory. Was the Regina Surgery Center, was  
15 that the first site that you recall doing  
16 work, research work in connection with the  
17 HotDog?

18 A. Yes, I think so. Yes.

19 Q. And I -- and I -- I don't mean to  
20 misrepresent it. I don't think this was  
21 actually specifically HotDog research, but  
22 research in the patient-warming area,  
23 clinical research?

24 A. I'll say yes.

25 Q. Okay. The -- now, there's a -- there's a

1 ALBRECHT

2 reference here in that very first paragraph  
3 under, "Test Objective," to, "Test protocol  
4 2007-044." Do you see that?

5 A. Uh-huh.

6 Q. That's obviously not -- well, I shouldn't say  
7 that. Strike that.

8 Is -- do you have access yourself to  
9 test protocol 2007-044?

10 A. These are all company property, so no.

11 Q. Is that a document that you would expect  
12 to -- to still exist at the Augustine  
13 Biomedical & Design Company?

14 MR. B. GORDON: Objection; calls  
15 for speculation.

16 THE WITNESS: Let me read through  
17 this carefully, if you don't mind.

18 MR. C. GORDON: Please do.

19 THE WITNESS: If I have a little  
20 bit of time --

21 MR. C. GORDON: Absolutely. I'm  
22 going to ask you some questions about it, so  
23 that's a good idea.

24 THE WITNESS: (Reviews document.)  
25 Yeah, I would expect that protocol to exist

1 ALBRECHT

2 at the company, yes, 2007-044.

3 MR. C. GORDON: Okay.

4 THE WITNESS: And so I would  
5 imagine that the date on that would be before  
6 the date on this, one would think.

7 BY MR. C. GORDON:

8 Q. Would you have -- do you recall having any  
9 input or involvement in the development of  
10 the -- of the protocol that was implemented  
11 in this particular test?

12 A. I would have to see the protocol to know.  
13 This is a while back in time.

14 Q. Sure. Do you -- did you actually go to the  
15 Regina Surgery Center in Hastings?

16 A. Yes.

17 Q. And you did some testing in their operating  
18 rooms, right?

19 A. Uh-huh. Yes.

20 Q. Was that the first time you had done any  
21 testing in actual operating rooms?

22 A. I believe so.

23 Q. And we'll -- we'll get into the details, but  
24 would it be a gross but fair characterization  
25 that there were two areas of testing, one was

1 ALBRECHT

2 the ambient OR air and the HVAC system at the  
3 hospital, and the other was the Bair Hugger  
4 warming units that were there?

5 A. Yes.

6 Q. Okay. What -- what was the genesis of this  
7 research? How did -- how did this come to  
8 pass?

9 A. Why were we investigating operating theater  
10 airflows?

11 Q. Yes, start with that.

12 A. Sure. Physicians had mentioned through  
13 feedback channels that came into the company  
14 that they'd feel warm air flowing around the  
15 operating theater and they wanted, and  
16 orthopedics particularly, and I can't  
17 remember any of the names, because this is  
18 just general feedback that kind of filters  
19 in, were a little concerned because they care  
20 a lot about their laminar ventilating flow  
21 fields. And so the question was how does  
22 this stuff work and, you know, where -- we  
23 wanted to get an understanding of ventilation  
24 systems and how any hot air might be  
25 interacting with them based on that feedback.

1 ALBRECHT

2 Q. So this was prompted more by your -- and by  
3 "your" I mean Augustine Biomedical's  
4 interests, as opposed to the hospital asking  
5 for -- for particular inspection or -- or  
6 analysis?

7 MR. B. GORDON: Object to form.

8 By the way, I may object from time  
9 to time. It's just for the record. You can  
10 go ahead and answer unless someone says  
11 otherwise.

12 THE WITNESS: No, this was  
13 following physician feedback and just  
14 investigating if something was there.

15 BY MR. C. GORDON:

16 Q. So one of the things you did was to measure  
17 actual airflow from the -- the HVAC system;  
18 is that correct?

19 A. Correct.

20 Q. Was -- do you recall, was the surgery center  
21 in Hastings, was that a laminar system?

22 A. I do not believe that one was. I'm unsure  
23 though.

24 Q. Do you know why Hastings was selected for  
25 your work?

1 ALBRECHT

2 A. We had physician contacts there that we could  
3 access the operating rooms through and the  
4 hospital staff was willing to work with us.

5 Q. Was this one that Dr. Gauthier was the  
6 primary contact?

7 A. He had put us in touch with the hospital  
8 administration.

9 Q. Okay.

10 A. So he was involved in facilitating it, yes.

11 Q. So one of the things you did was to use an  
12 optical particle counter to count, measure  
13 the number of particles in the -- in the air  
14 in the operating room; is that correct?

15 A. Yes.

16 Q. And you also did some bacterial culturing to  
17 see if there were colony-forming units or  
18 CFUs of bacteria in the ambient air; is that  
19 correct?

20 A. Yes.

21 Q. And do you recall that one of the -- you  
22 found that there was a problem with the  
23 Hastings HVAC system?

24 A. Yes. Uh-huh.

25 Q. Why don't you tell me what the problem was

1 ALBRECHT

2 that you found out.

3 A. I believe that their plenums, the filter was  
4 pushed out and not operating correctly.

5 Q. And some day this may be played back to a  
6 jury and there may be one or two people who  
7 don't know what a plenum is, or me too.

8 Could you explain what a plenum is?

9 A. I believe there was a leak in their  
10 filtration system where it was bypassing the  
11 filter is what the cause was identified as  
12 their engineering group.

13 What we did is we presented to them  
14 the results that here are the counts and  
15 their engineering team went in there and did  
16 a remedial action. I don't recall exactly  
17 what it was that the design flow was, and it  
18 might be written down in the report. If you  
19 have that handy I would like to see it and I  
20 can further elaborate on what it is.

21 Q. I may. Help me out here.

22 (Whereupon, Exhibit 2 was  
23 marked for identification.)

24 BY MR. C. GORDON:

25 Q. I'll give you what's marked as Exhibit 2 --

1 ALBRECHT

2 A. Okay.

3 Q. -- titled as, "Hastings Ventilation  
4 Assessment." And I'm not -- I'm not  
5 representing that this is the report from  
6 Exhibit 1, but you tell me, basically.

7 A. I don't have my name on this.

8 MR. B. GORDON: So that's the  
9 question, is this the report?

10 MR. C. GORDON: Yeah.

11 BY MR. C. GORDON:

12 Q. Is this -- is Exhibit 2 the report that would  
13 have been generated from the research that's  
14 referenced in Exhibit 1?

15 A. Let's take a look through here.  
16 (Reviews document.)

17 I believe this was the report that  
18 we had provided them to identify the problem  
19 upon which they took action.

20 Q. Okay.

21 A. So I think the source data for this report  
22 did likely come from this.

23 Q. And so the record is clear, the source data  
24 in Exhibit 1 is what the Exhibit 2 was based  
25 on?



1 ALBRECHT

2 A. To the best of my knowledge.

3 Q. Okay. So Exhibit 1 would not have been  
4 provided to Hastings, that was an internal  
5 document?

6 A. Yes.

7 Q. Okay. Going back to Exhibit 1, let's -- I  
8 want to talk about the measurements that were  
9 performed on the convective-warming units.  
10 First of all, when it refers to  
11 convective-warming units, that -- those are  
12 Bair Hugger units, right?

13 A. We'd have to look at the list of units  
14 sampled, but I believe they all were.  
15 (Reviews document.) Yes.

16 Q. Generally, you've done a number of research  
17 projects and studies involving Bair Hugger,  
18 correct?

19 A. Uh-huh. Yes.

20 Q. Have you -- as you sit here today, can you  
21 recall any research projects that involved  
22 other forced-air warming devices other than  
23 the Bair Hugger unit?

24 A. I believe in Europe we did look at some of  
25 the filter flow blowers. I do not recall if

1 ALBRECHT

2 they ever made it into the studies.

3 Q. Okay. In terms of the -- well, strike that.

4 You -- what you did in Hastings, you  
5 did similar things in other hospitals in the  
6 United States, correct?

7 A. Yes.

8 Q. And in those other hospitals in the  
9 United States, if you looked at a forced-air  
10 warming device, it was always the  
11 Bair Hugger, right?

12 A. I believe so, yes.

13 Q. Okay. Going back to Exhibit 1 now, so you --  
14 it looks -- you did four things in looking at  
15 the -- the Bair Hugger units. The first  
16 would be you did optical particle counting  
17 by -- and counting particles that were  
18 coming --

19 A. Yes.

20 Q. -- out of the airstream, correct?

21 A. Yes.

22 Q. Number two, you -- you did what's referred to  
23 as swabbing and plating, where you took swabs  
24 from the outside of the intake filter and  
25 inside the hose and then those swabs were

1 ALBRECHT

2 then cultured out on -- on plates to see if  
3 they had bacteria, right?

4 A. Correct.

5 Q. And then you did a -- something referred to  
6 as liquid extraction and plating where the  
7 hose of the Bair Hugger was rinsed with a  
8 sterile liquid and then that liquid, with  
9 whatever it mobilized from inside the hose,  
10 was cultured to see if there were any  
11 bacteria, correct?

12 A. Correct.

13 Q. And finally you did --

14 A. I want to stop. On three, I didn't do that  
15 necessarily.

16 Q. Okay.

17 A. Pace Analytical ran those results.

18 Q. Pace Analytical did the actual culturing; is  
19 that right?

20 A. Well, we brought a technician on-site too to  
21 do a lot of the liquid extraction.

22 Q. Okay. So liquid -- the actual liquid  
23 extraction itself was done by Pace?

24 A. On a number of the studies, I believe.

25 Q. How about the swabbing, who did that?

1 ALBRECHT

2 A. On the studies -- I believe Pace did it on  
3 the studies. I'm trying to recall, but I did  
4 bring one of their technicians on-site to do  
5 those activities.

6 Q. Okay. And whatever was taken out of the --  
7 with the swabs or the rinse, that was  
8 analyzed then off-site on -- in Pace's --

9 A. Yes.

10 Q. -- laboratories?

11 A. Yes.

12 Q. And then Augustine Biomedical would have  
13 gotten some sort of written report from Pace;  
14 is that correct?

15 A. Yeah.

16 Q. And the fourth thing you did with Bair Hugger  
17 units in Exhibit 1 was impaction sampling of  
18 the airstream of the Bair Hugger, right?

19 A. Uh-huh. Yup.

20 Q. Could you explain what impaction sampling  
21 was?

22 A. Yeah. We rented a device that takes an  
23 airflow that it brings into it and it fires  
24 it into a gel medium to see if there's any  
25 airborne bacterium and the idea is that it's

1 ALBRECHT

2 designed in such a way that it captures those  
3 on the agar plate with a reasonable  
4 efficiency.

5 Q. So you were looking for particles coming  
6 out, that were being blown out of the  
7 Bair Hugger --

8 A. Uh-huh.

9 Q. -- right --

10 A. Yes.

11 Q. -- that was the particle counting?

12 But with the impaction counting you  
13 were looking to see if there were any actual  
14 bacteria that were being blown out of the  
15 Bair Hugger?

16 A. Correct.

17 Q. And the other, the swabbing and the liquid  
18 extraction, that was to see if there was any  
19 bacteria inside the Bair Hugger?

20 A. Resident, yes.

21 Q. Resident bacteria, okay.

22 And if you would turn to page 4 of  
23 Exhibit 1, that reflects the -- there are two  
24 tables there, but the top table, table 2,  
25 that reflects the -- the results from the

1 ALBRECHT

2 impaction --

3 A. You're looking at page 5? I'm sorry.

4 Q. I think it's page 4 of 11.

5 A. Page 5 of 12, 4 of 12.

6 Q. Maybe we're looking at the wrong thing. I  
7 may have the wrong copy.

8 MR. ASSAAD: I have 12 as well.

9 MR. B. GORDON: Yeah, same here.  
10 Do you have a different version?

11 MR. C. GORDON: Apparently I do.  
12 May I see your version?

13 THE WITNESS: (Hands document.)

14 MR. C. GORDON: Oh, yeah,  
15 something is different here. That's weird,  
16 the text looks the same, but for some reason  
17 it's different pagination.

18 MR. ASSAAD: What's the Bates  
19 number that you're looking at?

20 MR. C. GORDON: 000157.

21 MR. ASSAAD: Just 157?

22 MR. B. GORDON: 77?

23 MR. C. GORDON: Through 1588. The  
24 page I want to talk about now is 1581.

25 Thank you for calling that page --

1 ALBRECHT

2 THE WITNESS: Sure.

3 MR. C. GORDON: -- discrepancy to  
4 my attention.

5 BY MR. C. GORDON:

6 Q. So the table -- it still says table 2, right?

7 A. Yes.

8 Q. And those are the -- that -- that table 2  
9 there is the -- reflects the results of the  
10 impaction testing from what was actually  
11 coming out of the Bair Hugger, right?

12 A. Yes.

13 Q. And in describing the impaction results --  
14 first of all, who -- strike that.

15 Who actually authored the -- the --  
16 the text that's in here?

17 A. Well, my name is on it, so it's probably  
18 myself.

19 Q. Okay. So in describing what's shown in table  
20 2, you -- you said, "Little or no growth  
21 occurred on the agar plates"; is that  
22 correct?

23 A. In this situation it appears that way. There  
24 are standards you can reference for what they  
25 allow for impaction, I believe. It's been a

1 ALBRECHT

2 while since I've looked at the standards for  
3 the European ventilation tests. Most of  
4 these tests come from European sources.

5 Q. Why is that?

6 A. Because the NHS, they have stricter  
7 guidelines on their operating construction  
8 and testing there, I believe, than here.

9 Q. So when you say the NHS, you're talking  
10 about the National Health Service in the  
11 United Kingdom?

12 A. I believe so.

13 Q. Okay. So and in -- were the impaction -- was  
14 the impaction testing that you did on the --  
15 the Bair Hugger airstream, was that an  
16 attempt to find out if the -- the air coming  
17 out of the Bair Hugger would -- would comply  
18 with NHS standards?

19 A. I don't believe there are NHS standards for  
20 convective-warming equipment, but we were  
21 just observing what would be there. This is  
22 one of the earlier studies and we were unsure  
23 as what would even be found.

24 Q. And -- so, basically, to -- to kind of put it  
25 in simplistic terms, you're looking at three



1 ALBRECHT

2 things with respect to the Bair Hugger,  
3 particles that were coming out of it, bugs  
4 that were resident inside of it, and bugs  
5 that were coming out of it?

6 MR. B. GORDON: Object to form.

7 BY MR. C. GORDON:

8 Q. Is that accurate?

9 A. We were assessing filtration efficiency and  
10 that dealt with particles on the in and out  
11 stream, because that's very important in case  
12 there are resident airborne microbes that  
13 could be sucked in and delivered through.

14 We were looking to see if there were  
15 resident bacteria in the Bair Hugger or  
16 anything pathogenic. And we were interested  
17 in whether or not those were on the surfaces  
18 or whether we could detect them in the  
19 airflow.

20 Q. Okay. And, basically, you couldn't detect  
21 them in the airflow, correct?

22 A. In this study I don't see high counts, so,  
23 yes, it looks like they were -- well, we did  
24 have one or two counts, it looks like, but  
25 the control also had a count.

1 ALBRECHT

2 Q. Okay. So there were -- it looks like there  
3 were three Bair Huggers sampled?

4 A. Yup.

5 Q. Tell me what the -- the different sampling  
6 things mean there. There are -- for example,  
7 on the first one there's three actives and  
8 then there's a control. What's -- what do  
9 those mean?

10 A. So one would be sampling the air out of the  
11 Bair Hugger three times, and then the control  
12 I think would be an ambient sample of the  
13 operating theater air.

14 Q. Okay.

15 A. And I'd have to read carefully if you want a  
16 very precise answer.

17 Q. Actually, I do on this, yeah.

18 A. All right. (Reviews document.)

19 Okay. Go ahead and reask me the  
20 question.

21 Q. I'm just trying to understand the different  
22 counting lines. For example, in the first  
23 one for the Bair Hugger 505 CW 19808, the  
24 first line says, "Active," and under, "Sample  
25 start time," it says, "Zero," in brackets,

1 ALBRECHT

2 "Seconds," and then there's a, "CFU/Volume  
3 Sample" --

4 A. Yup.

5 Q. -- and that's 1. What is the -- and then on  
6 the next -- the next line under that it's --  
7 under, "Sample start time," it's 1,276 --

8 A. Yup.

9 Q. -- but the impaction volume is --

10 A. Less.

11 Q. -- 625 versus a thousand. I'm trying to  
12 understand what -- what's the difference  
13 between the sample start time of zero and  
14 then 1,276 seconds, and then the next one is  
15 2,103.

16 A. Yeah. So it's kind of coming back to me.  
17 It's been a while since we've done this.  
18 There's an argument of when you do impaction,  
19 how much air do you sample, what dries out the  
20 plates type of thing. So there's some  
21 guidance on how much you should be pushing  
22 into the agar plates. And so I believe in  
23 this case we tried -- it looks like it was  
24 varied in some kind of order. We tried three  
25 different levels of impaction sampling

1 ALBRECHT

2 different air amounts, so we sampled a  
3 thousand liters, 625, 250.

4 The sample start time, I believe  
5 that was just a value that was put in there  
6 to correlate with the particle counting to  
7 help join the tables in the information  
8 that's presented.

9 Q. So it doesn't -- the zero -- zero start time,  
10 that isn't when you -- the machine was first  
11 switched on, or is it?

12 A. The pump itself. The convective-warming unit  
13 may have been running ahead of time.

14 So there's -- this is a complicated  
15 apparatus, so it's got a huge, like,  
16 compressor, right, to draw the air through  
17 the impaction plate, and that gets turned on  
18 and off, the agar plate is positioned into it  
19 and that has got to be switched out, you  
20 know, a couple of times. And then how long  
21 you leave the apparatus on as you're blowing  
22 air into it, that is what this timer is  
23 related to, I believe.

24 Q. Let's take a detour for a minute, because  
25 I -- I'm not understanding this machine.

1 ALBRECHT

2 An agar plate, you know, in layman's  
3 terms, it's kind of like just, basically, a  
4 Petri dish that's got some gucky stuff in  
5 it --

6 A. Yes.

7 Q. -- that collects whatever is blown into it or  
8 poured into it or placed in it?

9 MR. B. GORDON: Object to form.

10 THE WITNESS: A Petri dish, if  
11 left out in just a room or whatever, would  
12 settle into it. That's not necessarily the  
13 airborne contaminants that are always -- it's  
14 not an efficient way of sampling.

15 BY MR. C. GORDON:

16 Q. So in -- in -- one way of seeing what's  
17 coming out of the Bair Hugger hose would be  
18 to just hold it over an agar plate and  
19 blow -- blow air right into the agar plate,  
20 right?

21 MR. B. GORDON: Object to form.

22 THE WITNESS: One could do that.

23 BY MR. C. GORDON:

24 Q. That's -- apparently, that's not what this  
25 is?

1 ALBRECHT

2 A. No, it's a more scientific method.

3 Q. All right. So that's -- can you explain to  
4 me how that works, because I was thinking it  
5 was more just blowing it right onto an agar  
6 plate.

7 A. Sure. So the setup, the actual interesting  
8 piece of it, it's this aluminum  
9 hockey-puck-looking disk that an agar plate  
10 goes into, and on top of it there's a grid.  
11 And this grid has small holes drilled into it  
12 and you apply a vacuum to that to get the air  
13 moving very fast.

14 And the idea is if particles are  
15 trapped in a fast-moving airstream and you  
16 turn it, the momentum of the particle will  
17 carry it into the agar dish. So it's an  
18 efficient means sampling airborne particles,  
19 whether you want to get that to impact on a  
20 plate or bacterium to impact on a plate,  
21 different things like that, you can capture  
22 it with higher efficiency than just setting  
23 out a dish.

24 Q. Does the suction or the vacuum on the  
25 apparatus create a pressure differential

1 ALBRECHT

2 between the -- the airstream as it's coming  
3 out and the apparatus for the agar plate?

4 A. Yes. It samples air at a certain rate. I  
5 would have to look at what it draws through,  
6 but they are calibrated when this pump is  
7 running in the device that it'll pull in a  
8 given amount of air volume to sample. And so  
9 you've got a hose blowing out a much greater  
10 supply of air than what this device is  
11 designed to pull in, so it's sampling a  
12 fraction of the air that's coming out of the  
13 convective-warming unit.

14 Q. And it's basically sucking out whatever  
15 portion of that air it's sampling, right?

16 A. It's pulling the air in, and once it has it  
17 captured in the device, then it accelerates  
18 it very quickly through those little pinholes  
19 we talked about. And then as the air turns  
20 out of the agar, it lets it deposit things  
21 more efficiently into the agar than just  
22 simply setting a plate out in the room.

23 Q. And what's the significance of the different  
24 impaction volumes, why -- why would you  
25 get -- why would you want to use a thousand

ALBRECHT

or 625 or 250?

A. There's some suggestion that it can dry out the agar dish. There's some other suggestion --

Q. If it's too high?

A. If there's too long of a jet put going on, yes. If you run too much air through, it can dry it out. These airstreams are also very damaging to what they're collecting, because they're high velocity, so they have been known at times to rip the bacteria apart. And so even though you're collecting things, they may not survive, and so it's to limit the balance of that.

Q. So was this the same apparatus, then, that was used for the operating room HVAC ventilation results? I think it's --

A. Do you have the test protocol 2007-044?

Q. No, I don't. I'd like to.

A. Okay. Because the complete description of that should be provided there.

Q. Yeah, I agree.

A. Because this alone by itself is somewhat incomplete.



1 ALBRECHT

2 Q. Okay. If you flip ahead, like, five pages  
3 to -- I guess is it 9 of 11, where it says,  
4 "OR HVAC ventilation results"?

5 A. I've got 9 of 12. Yes.

6 Q. Nine of 12, I'm sorry.

7 And there it looks like there were  
8 five different measurements in the OR itself?

9 A. There's four different operating theaters  
10 that were measured.

11 Q. Oh, four different operating theaters. Okay.

12 A. There were two measurements in one of the  
13 rooms, it looks like.

14 Q. Okay. And in each case, was it the same  
15 apparatus that was used? That's what I'm  
16 asking.

17 A. Yes.

18 Q. Okay. So in each of these cases, each of  
19 these five measurements, the impaction volume  
20 was a thousand liters?

21 A. Yes.

22 Q. And it looks like -- so in the first three  
23 operating rooms --

24 A. They were at rest.

25 Q. They were -- the laminar -- or the --

1 ALBRECHT

2 whatever the HVAC system was, it wasn't  
3 turned on?

4 A. There were no personnel in the room.

5 Q. Okay.

6 A. So at rest refers to no occupants in the  
7 room.

8 Q. So in that -- the first three rooms, that  
9 apparatus with the agar plates got no  
10 bacteria, right?

11 A. Correct.

12 Q. But in operating room 4 there were two  
13 different measurements, one was at the center  
14 of the operating room table, and there were  
15 19 bacterial colony-forming units measured;  
16 is that right?

17 A. Yes. And that is in an operating room under  
18 working conditions with personnel moving  
19 around.

20 Q. Oh, okay.

21 A. So it's not at rest. So that's the  
22 difference between --

23 Q. I see.

24 A. -- 1 through 3 and 4.

25 Q. Did you -- do you recall if you did tests of

ALBRECHT

1, 2, 3 -- 1, 2 and 3 where -- with working personnel?

A. We did not. Those were tested at rest and we intentionally chose a room with people working to see if there -- if this equipment was sensitive.

Q. And if -- when you say they were working, were they -- were these real surgeries that were going on or just people moving in and out?

A. We may have had the staff perform a mock surgery, I'm guessing. I need to look carefully here to answer that.

Q. Okay.

A. (Reviews document.) So the detail is operating room 4 was sampled as a working room with two occupants moving about. From my memory, I'm unsure if I had asked the surgical staff to do that or if I had some of the personnel there who were gowned up similarly walking around, I'm unsure.

Q. So having two people moving within operating room 4 when you took the same measure -- same type of measurements, in one case there were

ALBRECHT

19 bacteria colony-forming units on the table, and in the other measurement 12 inches from the ceiling where the air was -- would be -- clean air was coming in; is that right?

A. Yes.

Q. There were five colony-forming units?

A. Correct.

Q. Was the Bair -- was there a Bair Hugger on during these measurements?

A. No.

Q. Okay. These are measurements of a -- of a -- of an OR with its ventilation system -- I'm sorry, was the ventilation system on?

A. Yes.

Q. Okay. And just two people moving -- moving around inside the OR, and you got 19 CFUs and 5 CFUs respectively?

A. In a turbulent ventilation system, which this is called out as, yes.

Q. Okay. And turbulent is different from laminar?

A. Very much so.

Q. I'm trying -- so help me correlate here. You also did particle sampling. Was that done at

1 ALBRECHT

2 the same time as the -- the impaction  
3 sampling?

4 A. So if I recall correctly, this is five years  
5 ago, once again, or more, so your memory  
6 isn't always a hundred percent, we had a  
7 fitment design that I think sampled both at  
8 the same time. So we had an apparatus that  
9 would hook to the edge of the Bair Hugger, a  
10 hose or the convective-warming unit, and then  
11 a sample for particles was drawn concurrently  
12 with the impaction sample.

13 Q. Okay. How about in the OR when you -- if you  
14 look to --

15 A. These were all tested in the OR.

16 Q. I'm talking about the OR air, I'm sorry.

17 If you look at the table of page 10  
18 of 12, table 8, it looks like particle counts  
19 in those same four operating rooms.

20 A. So this is prior particle counts, if you read  
21 the table subscript in table 8.

22 Q. What does prior mean in this context?

23 A. So we were there two times to that site, once  
24 with the ventilation system where it had an  
25 issue and then once after it was corrected.

ALBRECHT

Q. So table 7, would that have been the first time or the second time?

A. Second time, I believe.

Q. So table 7 reflects after the problem with the ventilation system was corrected?

A. To the best of my knowledge, yes.

Q. Okay. So is table 5 the one that would show the particle counts in the OR -- ORs that correspond to table -- the impaction results, table 7?

A. I would -- yes, I would conclude that.

Q. So in operating room 1, for example, there are four different measurements, three of them a little bit higher than 22,000, and one of them 19,500; is that right?

A. Correct.

Q. And those were particles greater than .3 microns, right?

A. Yup. Yes.

Q. And -- but particles greater than .5 microns in operating 1, those were generally around a thousand?

A. Yes.

Q. Basically, the difference between the

1 ALBRECHT

2 point -- the particles greater than .3  
3 microns was about roughly 20 times as many as  
4 the particles greater than .5 microns?

5 A. Yes.

6 MR. B. GORDON: Object to form.

7 BY MR. C. GORDON:

8 Q. And in operating room 1, at least, particles  
9 greater than 5 -- 5 microns, three of the  
10 four measurements were 0, but one of them was  
11 60; is that right?

12 A. Correct.

13 Q. So there -- why -- why did you do  
14 different -- the measurements of particles at  
15 greater than .3, greater than .5 and greater  
16 than 5?

17 A. That's all simultaneously reported by the  
18 device. So this is its native output. So  
19 the sampler, the laser -- laser air particle  
20 counter, it measures a count of these things  
21 simultaneously. This is the raw data output.

22 Q. What are the sizes of -- of bacteria?

23 MR. B. GORDON: Object to form.

24 THE WITNESS: It depends. They  
25 come in many ranges.

1 ALBRECHT

2 BY MR. C. GORDON:

3 Q. Well, what's the smallest bacteria that you  
4 are aware of?

5 A. In some of the research studies we highlight  
6 that very carefully, and so I'd like to point  
7 to one of those documents. If you'd like to  
8 pull some of those out I can -- I'm aware of  
9 them, though, I believe, and I'll have to  
10 check because it's been a while, .5 microns  
11 is a size that can be a bacteria.

12 Q. Okay. Does that look like one of the ones  
13 that might have that information,  
14 (indicating)?

15 A. Possibly.

16 Q. Or -- well, that would be my best guess.

17 MR. B. GORDON: Well, if he needs  
18 studies to answer a question --

19 THE WITNESS: I do.

20 MR. B. GORDON: -- just give them  
21 to him.

22 MR. C. GORDON: No, no, I just  
23 want to give him the right one.

24 MR. B. GORDON: Maybe he can pick  
25 from your stack.



1 ALBRECHT

2 THE WITNESS: I have a reference  
3 for that and I'd rather not speculate.

4 MR. C. GORDON: Sure.

5 BY MR. C. GORDON:

6 Q. In operating 4, operating room 4 on table 5,  
7 it looks like all the particle counts in  
8 the --

9 MR. B. GORDON: So before -- are  
10 you withdrawing that question, the prior  
11 question?

12 MR. C. GORDON: Yeah, we'll get  
13 the copies of the study and get back to that.

14 MR. B. GORDON: It was just  
15 hanging out there, I just want to be sure  
16 it's not on the table.

17 MR. C. GORDON: Yeah, I withdraw  
18 it if there's anything out there.

19 BY MR. C. GORDON:

20 Q. In the particle counts in operating 4, for  
21 the particles greater than .3 microns, the --  
22 the four -- the five different measurements  
23 look like they're roughly about 25 percent  
24 less than the particle counts in operating  
25 room 1; is that right?

1 ALBRECHT

2 A. That's what the data suggests, yes.

3 Q. And, similarly, in the particle counts  
4 greater than .5, they're somewhere between  
5 roughly half and 80 percent of the particle  
6 counts in that same range for operating room  
7 1; is that right?

8 A. Can you please repeat?

9 Q. The -- in the column for the greater than .5  
10 microns, the particle counts in operating  
11 room 4 are about somewhere between 50 and  
12 80 percent of the particle counts for that  
13 size range in operating room 1, right?

14 A. Fifty to 80 percent?

15 MR. B. GORDON: Objection to form,  
16 mischaracterizes the table.

17 THE WITNESS: I'm not exactly  
18 following, if you could phrase one more time.

19 BY MR. C. GORDON:

20 Q. Rather than quantifying them, would you agree  
21 that the -- that the particle counts you  
22 measured in operating room 4 were less than  
23 the particle counts in operating room 1?

24 A. The average of that, yes, but there is some  
25 dispersion to the data that overlaps. So if

1 ALBRECHT

2 you look, you can see, for example, at .5  
3 microns there's a count of 1,080, and that is  
4 above the range of the minimum that was  
5 measured in operating room 1 of 820.

6 So I'm not sure that they're -- what  
7 differences might exist looking at the spread  
8 of the data.

9 Q. Yeah. And as a statistician, you're going  
10 to -- you're going to be more concerned with  
11 the -- the spread of the data rather than  
12 just the raw numbers?

13 A. Correct.

14 Q. Okay. So just looking at this, you can't say  
15 whether these counts demonstrate that  
16 operating room 4 had more or less particle  
17 counts in the .3 and .5 range than operating  
18 room 1?

19 A. In the .3, I think it would. In the .5, I'm  
20 unsure.

21 Q. Can you -- are you -- are you confident,  
22 though, that .4 -- that the operating room 4  
23 in the .5 micron range, if you were to do the  
24 proper statistical analysis, wouldn't have  
25 more particles than operating room 1?

1 ALBRECHT

2 A. No, it would not.

3 Q. Okay. But if we go to the ventilation  
4 results, table 7 on page 9, the -- for the  
5 impaction, in operating room 1, which had at  
6 least as many particles, if not more than  
7 operating room 4, you got no bacteria. But  
8 in operating room 4 you counted 19  
9 colony-forming units in one case and 5  
10 colony-forming units in the other; is that  
11 right?

12 A. Let me make sure that operating room 4 was  
13 measured at the same time. So in looking at  
14 these tables, these particle counts in table  
15 5 may have been taken at a different time  
16 than the impaction results, if there's a  
17 working condition listed. Sorry, let me look  
18 through here. These are very complicated to  
19 look at.

20 Q. I'll stipulate to that.

21 A. (Reviews document.) Concurrent with  
22 impaction. Okay. So for the  
23 convective-warming units it was done  
24 concurrent, but I don't know about the  
25 operating theater.

1 ALBRECHT

2 MR. ASSAAD: Corey, are you  
3 looking at -- just I know we're on the same  
4 page, you're looking at page 9 of 12?

5 MR. C. GORDON: For the CFU --  
6 yeah, table 7.

7 MR. ASSAAD: For the CFU? Okay.

8 THE WITNESS: (Reviews document.)

9 MR. B. GORDON: While he's  
10 looking, I'm going to just put an objection  
11 on the record to the form in that the  
12 question is conflating particle counts in one  
13 table and colony-forming units in another  
14 table. I don't know if there's -- what the  
15 correlation is, but it seems --

16 MR. C. GORDON: Well, I'll  
17 stipulate that there isn't any. Do you want  
18 to stipulate to that?

19 MR. B. GORDON: Well, I object to  
20 the form of the question then, because I  
21 think it's a complex, confusing question and  
22 conflates two different data points. I'm not  
23 sure it can be answered, but...

24 THE WITNESS: So this was measured  
25 at rest near the ceiling.

1 ALBRECHT

2 BY MR. C. GORDON:

3 Q. Which -- which was measured at rest?

4 A. So these particle counts of the operating  
5 room ventilation system in table 5 were  
6 measured up inches from the plenum at the top  
7 of the ceiling in four locations.

8 Q. Okay.

9 A. This is when the room was at rest. At a very  
10 different time this impaction was done --

11 Q. Okay.

12 A. -- in the operating theaters, so these do not  
13 line up. Because if it's at rest, we can't  
14 be in there measuring the particles, because  
15 we'd be disturbing the field.

16 So how the experiment went, now that  
17 I've kind of got my head around this, it  
18 takes a long time, sorry, it's been seven  
19 years, you know --

20 Q. Honestly, that's partly why we're spending a  
21 lot of time on this one, because I thought it  
22 would get you back familiar with that,  
23 because I've got some other ones like this  
24 that --

25 A. Okay. So I will rehash what's here then just

1 ALBRECHT

2 so we're very clear.

3 So in table 5, this was all done at  
4 rest, and it followed a sampling pattern  
5 where you go to the ceiling of the room, and  
6 you're just below 7 foot 6, right above the  
7 floor, right, so you're 6 inches below four  
8 of the diffuser panels, and you measure each  
9 of them.

10 And the point of this is to make  
11 sure you know the air quality coming into the  
12 room. Now, these are done at rest, no one is  
13 in the room except for the technician with  
14 the particle counter over their head, so  
15 there shouldn't be any introduction of  
16 contaminants from a person's skin or things  
17 like that.

18 Now, here when we did the impaction  
19 to sample for airborne colony-forming units,  
20 these are rooms at rest. We're not in there  
21 sampling particles at that time for 1, 2 and  
22 3, we're out outside the room, we turn it on,  
23 we go kind of from the edge of the door and,  
24 you know, shut the door and don't let anybody  
25 go in there while it runs.

1 ALBRECHT

2 Q. Is the HVAC system on though?

3 A. It's always on.

4 Q. Okay.

5 A. They never turn those off.

6 In operating room 4, this was at a  
7 different time when the particles were  
8 counted, okay? So this was, like, maybe  
9 hours before. And people were in there for a  
10 mock surgery and we wanted to see if the  
11 device would detect colony-forming units in  
12 the air should there be personnel activity.

13 I'm sorry it took me a while to get  
14 this organized.

15 Q. And -- and -- and let me see if I understand.  
16 Hastings was -- was, as I understand it, an  
17 unusual situation where you discovered a -- a  
18 problem with the HVAC system?

19 A. We did.

20 Q. Was it -- do you recall that the Hepa filter  
21 was upside down?

22 A. No, it doesn't work like that, I don't  
23 believe.

24 Q. Okay.

25 A. It would be busted out of the frame that



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houses it so air could bypass, would be my guess what the problem was that they fixed.

Q. And looking at table 8, which you pointed out was the prior particle -- particle counts, it looks like --

A. Up by the top of the ceiling, yes.

Q. Right. Those -- and it looks like those were done on July 24th, 2007?

A. That looks correct.

Q. So those particle counts were over half a million each for the .3 --

A. Yes.

Q. -- as compared -- as compared to the -- you know, to those in the --

A. The proper level.

Q. -- the 20,000 range?

A. Yes.

Q. So there's a huge difference, right?

A. Yes.

Q. And so the table 5 represents a properly functioning ventilation system?

A. Properly functioning turbulent ventilation system.

Q. Okay. And with this properly functioning

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turbulent ventilation system, it's in the .3 micron range, each one of these ORs is putting out 10 to 20,000 particles every place that it's measured, right?

A. Yes, and the supplier and the ceiling coming in, correct.

Q. And -- and is that what you would expect in a properly functioning turbulent system?

A. There are guidelines on what's considered acceptable on European standards, and I believe this was within the limits for a turbulent system.

Q. Okay. So with a properly functioning turbulent system and thousands of particles being emitted from the -- the -- the HVAC system into the room, when you introduce -- when nobody is in the room, you can't -- you didn't culture out any bugs?

A. Correct.

Q. But when two people were in the room moving around, then you were able to culture out 19 CFUs in one case and 5 CFUs is in the other case?

A. Correct. Different kinds of particles are

1 ALBRECHT

2 likely in the air.

3 Q. Okay. So did it surprise you that, you know,  
4 with -- with -- with operating rooms 1 and 3  
5 having tens of thousands of particles being  
6 emitted, you couldn't culture out any bugs?

7 MR. B. GORDON: Objection to form,  
8 conflating particles and bugs again, but...

9 THE WITNESS: So to answer that, a  
10 large amount of the particles are going to be  
11 atmospheric dust that come in and so the --  
12 it is not exactly surprising, because  
13 atmospheric dust is not bacteria always, it's  
14 not, it's just particles that are in the air.

15 BY MR. C. GORDON:

16 Q. And -- and to Mr. Ben Gordon's objection,  
17 particles don't correlate to bacteria,  
18 correct?

19 A. Correct.

20 MR. B. GORDON: Object to form.

21 BY MR. C. GORDON:

22 Q. And in, you know, kind of in lay terms, if  
23 we -- if somebody looks at a window on a very  
24 bright, sunny day and you see a bunch of  
25 stuff in the air, if you close the shades

1 ALBRECHT

2 that stuff seems to disappear, it's not that  
3 that stuff is really disappearing, it's just  
4 that there's particles in the air that --  
5 that are not ordinarily visible to the naked  
6 eye, right?

7 MR. B. GORDON: Object to form.

8 I'm not sure what the question is.

9 THE WITNESS: Yes, there are  
10 particles that you cannot see with your eye.

11 BY MR. C. GORDON:

12 Q. And even in a clean surgical environment with  
13 a properly functioning turbulent system,  
14 there are going to be thousands of particles,  
15 right?

16 MR. B. GORDON: Object to form.

17 THE WITNESS: I would expect  
18 atmospheric dust to be present, yes.

19 BY MR. C. GORDON:

20 Q. So let's talk about the particles that you  
21 counted in the Bair Hugger. In this -- in  
22 the tests you did at Regina Hospital in  
23 Hastings, is that table 1, page 4 of 12?

24 A. Yes.

25 Q. And so the -- the measurements here are --

ALBRECHT

well, one of the things that these measurements were attempting to do was to determine filtration efficiency, correct?

A. Correct.

Q. So there's particles before the filter and particles coming out after the filter, right?

A. Correct.

Q. And then it's just a numerator and denominator to develop a percentage of efficiency, right?

A. Yes.

Q. Okay.

A. With a non-quantitative challenge. This is not how you'd properly rate the filter. They have other studies that pertain to that.

Q. Okay. In this -- in the case of what you're measuring at -- at the Regina Hospital, you were -- just as you did in the OR, you measured particles greater than .3 microns, greater than .5 microns, and 5 -- greater than 5 microns, right?

A. Yes.

Q. I should say greater than or equal to --

A. Yup.

1 ALBRECHT

2 Q. And in -- in -- in each case the measurement  
3 of the point -- of the greater than or equal  
4 to .3 microns was higher than the greater  
5 than or equal to .5 microns, right?

6 A. Correct.

7 Q. And I guess we can use the average. It  
8 was -- the average particles counted of the  
9 greater than .3 microns was about roughly  
10 five times as many as the greater than .5  
11 microns, right?

12 A. It depends on the measurement.

13 Q. I'm just looking at the average.

14 MR. B. GORDON: You're talking  
15 about the average of all the experiments or  
16 just the top one?

17 MR. C. GORDON: You know, that's a  
18 good point. I actually don't understand what  
19 the difference is.

20 BY MR. C. GORDON:

21 Q. At the bottom of this table it says, "Average  
22 counts with fitment concurrent particle  
23 counting and impaction," and then there's  
24 another line that says, "Average particle  
25 counts" -- "average counts particle counter

1 ALBRECHT

2 only held in distal hose end." What -- what  
3 do those two different things mean?

4 A. Sure. Let me look here. (Reviews document.)

5 So we did a control measurement just  
6 to make sure the impaction equipment wasn't  
7 causing any additional particles, and so we  
8 ran one where we concurrently sampled the air  
9 particles along with doing impaction, and we  
10 did a subsequent test where we just hand --  
11 held the rod device in the airflow stream.

12 Q. And what did you determine in terms of what  
13 you were trying to find out whether the  
14 equipment was having any affect on the  
15 measurement?

16 A. It appears that it wasn't, looking at the  
17 spread of the data.

18 Q. Well, help me out here. For the point -- the  
19 greater than or equal to .3 micron particles,  
20 it looks like the -- the two numbers are  
21 pretty close. But in the point -- greater  
22 than or equal to .5 numbers, it looks like  
23 one of them is an order -- roughly an order  
24 of magnitude higher than the other.

25 A. On the average it is. But I'm looking,

1 ALBRECHT

2 again, at the spread of the data.

3 Q. Okay.

4 A. Let me look at this. (Reviews document.)

5 Q. And -- and help -- help me out with the  
6 spread, because if --

7 A. No, I'm assessing it right now.

8 Q. Oh, okay.

9 A. Just give me a second to look.

10 Q. Absolutely.

11 A. (Reviews document.) There's a really large  
12 range to what we're seeing here. So in some  
13 of the experiments with the impaction, the  
14 counts around 20, 21, and other ones I see it  
15 as high as 700, and so I'm not sure what the  
16 process that's generating that, but it  
17 doesn't follow -- follow any kind of like the  
18 normal statistical patterns. You shouldn't  
19 be able to have counts bouncing around that  
20 much if it's the same thing over and over.  
21 So I'm unsure of any conclusion I can make on  
22 that.

23 Q. Kind of a Heisenberg uncertainty principle of  
24 particle measurements?

25 A. It's not that. It's -- maybe there's slight



1 ALBRECHT

2 changes in the experimental setup, maybe  
3 there's something different with what's going  
4 on in the room, you just don't know.

5 Again, these studies were not  
6 designed to detect statistical differences  
7 necessarily on this set of them. This  
8 doesn't have, like, a sampling plan or  
9 anything in place that's a stat plan, other  
10 ones do.

11 Q. You did that, yeah, we'll get to -- that was  
12 done later.

13 So, basically, you were just looking  
14 to see are there any particles coming out  
15 and, you know, what -- in the -- in the -- in  
16 the three different size ranges?

17 A. Correct.

18 Q. And that's what you looked at in the OR  
19 ventilation system as well, right?

20 A. You do, but the source of particles are  
21 anticipated to be a little different. You  
22 know, the OR ventilation system is filtering  
23 out largely atmospheric dust as it comes from  
24 the outside.

25 The operating room has a very

1 ALBRECHT

2 different particle source that would be  
3 pulled into these units and put through, and  
4 that is -- a lot of the dust matter that you  
5 find in the actual operating theater after  
6 the atmospheric stuff has been cleaned  
7 relates to shed skin cells.

8 So the sources of the dust that the  
9 filters are acting on is different and so  
10 it's hard to draw conclusions and draw  
11 parallels between atmospheric dust when one  
12 system is intended to filter that out and  
13 skin cells and another system that's kind of  
14 pointed at a different kind of dust that it's  
15 assuming would be in the environment.

16 Q. Okay. Did -- so you -- you found that there  
17 were particles of various sizes, various  
18 counts coming out of the Bair Hugger?

19 A. We did.

20 Q. But you really didn't find much in the way of  
21 bacteria coming out?

22 A. We did not.

23 MR. B. GORDON: Object to the  
24 form.

25 MR. C. GORDON: Okay.

1 ALBRECHT

2 BY MR. C. GORDON:

3 Q. Did that surprise you?

4 A. No. We were unsure what we were looking for.  
5 We had no prior assumptions on what we should  
6 even expect.

7 Q. So --

8 A. What surprised me was the operating theater  
9 counts that we saw here that they needed to  
10 do a corrective action.

11 Q. Sure.

12 A. That was the surprising finding.

13 Q. So on this, which was probably the first  
14 study you did on Bair Huggers, you found  
15 particle emissions, but not much in the way  
16 of bacteria, virtually no bacteria?

17 A. In this study the counts were not elevated.

18 Q. Okay. With all that -- well, let me -- let  
19 me just actually -- actually ask you,  
20 Exhibit 2, the Hastings ventilation  
21 assessment, I'm -- I'm wondering about that  
22 second line. It says, "To get conclusive  
23 data, we analyzed three interrelated areas,  
24 the operating room's ventilation system air  
25 quality, the Bair Hugger unit's quality, and

1 ALBRECHT

2 the presence of microbes within the  
3 Bair Hugger units."

4 MR. B. GORDON: You left out the  
5 word "air."

6 MR. C. GORDON: Thank you.

7 BY MR. C. GORDON:

8 Q. Do you want me to -- I'm just calling your  
9 attention to that sentence. I can read it  
10 again if you want, but it's -- it's the three  
11 things that are being referenced there, the  
12 air -- air quality from the OR ventilation  
13 system, the Bair Hugger unit's air quality,  
14 and microbes inside -- within the -- or  
15 microbes within the Bair Hugger unit, right?

16 A. Yes.

17 Q. But, actually, you looked at four things,  
18 right, when you -- when you did the study,  
19 you -- you looked at the operating room  
20 ventilation air quality, you looked at the  
21 Bair Hugger air quality, you looked at the  
22 presence of microbes within the Bair Hugger,  
23 and you looked at the presence of microbes  
24 coming out of the Bair Hugger in its  
25 airstream, right?

1 ALBRECHT

2 A. So I'm unsure if this report was prior to  
3 this that you see here. This could have been  
4 generated off a different set of data that  
5 wasn't formally published. I'm trying to  
6 understand the order of events in my head as  
7 this relates to this. I know this test data  
8 spurred us to take action with them. And we  
9 obviously couldn't have had the final result  
10 until -- let me look through this one more  
11 time. (Reviews document.)

12 Q. And in fairness, you weren't certain that  
13 Exhibit 2 was -- was the report that emerged  
14 from Exhibit 1, so...

15 A. I'm unsure.

16 Q. And we'll leave it at that for now.

17 (Whereupon, Exhibit 3 was  
18 marked for identification.)

19 BY MR. C. GORDON:

20 Q. We'll show you what's been marked as  
21 Exhibit 3. And I'm going to ask you several  
22 questions about this, so if you want to take  
23 the time to review it, that's fine.

24 A. (Reviews document.) Okay.

25 Q. Okay. This Exhibit 3 is a document dated

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2 October 12th, 2007, and compiles results from  
3 three different hospitals, including the  
4 Regina Surgery Center in Hastings that we  
5 just spent some time looking at, right?

6 A. Uh-huh.

7 Q. Yes?

8 A. Yes, yes.

9 Q. And the -- the results we've gone over from  
10 the -- the Regina Surgery Center, those are  
11 contained in Exhibit 3, correct?

12 A. I see elements of them there, yes.

13 Q. Okay. And in addition, there are two other  
14 hospitals, the DC Hospital in Alexandria and  
15 the St. Cloud Hospital in St. Cloud?

16 A. Correct.

17 Q. Now, if you would turn to page 7 of 9 -- I'm  
18 sorry -- well, yeah, 7 of 9.

19 A. Table 4?

20 Q. Say again?

21 A. Table 4?

22 Q. Yes, table 4. This is the -- this table  
23 shows the number of colony-forming units that  
24 you -- you cultured out from each -- each of  
25 the Bair Huggers from these three hospitals

1 ALBRECHT

2 using swabbing and liquid extraction,  
3 correct?

4 A. Correct, the internal surfaces, yes.

5 Q. The internal surfaces of the -- it looks like  
6 three different Bair Huggers at each of the  
7 hospitals; is that right?

8 A. Correct.

9 Q. And in -- in all but three of the  
10 measurements you found somewhere between 1  
11 and greater than 300 CFUs, right?

12 A. It looks like 0 is one that was found too, so  
13 between 0 and greater than 300.

14 Q. Well, am I reading this right that there  
15 were -- at the Bair Hugger ones at -- at the  
16 Regina -- the Hastings hospital, the CFUs  
17 from the swabbing and extraction from the  
18 internal surfaces from those three  
19 Bair Hugger range from 1 to 7 -- 1 to 8  
20 colony-forming units?

21 A. Correct.

22 Q. And at Alexandria one of the swabs had 0 --

23 A. Correct.

24 Q. -- but all of the other measurements ranged  
25 from 2 to 102?

1 ALBRECHT

2 A. Correct.

3 Q. And at St. Cloud Hospital, it looks like two  
4 of the measurements, one a swab of one and  
5 one a liquid extraction of another  
6 Bair Hugger, had 0, but the others ranged  
7 from 1 to greater than 300?

8 A. Correct.

9 Q. So that -- those are the internal surfaces,  
10 right?

11 A. Correct.

12 Q. And then table -- I guess it's table 3 on  
13 page 5.

14 A. Okay.

15 Q. Those were the particle counts that you  
16 measured for those same Bair Hugger units,  
17 right?

18 A. Let me just make sure the numbers line up  
19 here. (Reviews document.) So Regina 14,503.  
20 That looks correct.

21 Q. And, you know, for example, the particles  
22 that are greater than .3 microns, it looks  
23 like the lowest number is 148 and --

24 MR. B. GORDON: Which hospital are  
25 you talking about or are you talking about



1 ALBRECHT

2 all of them?

3 MR. C. GORDON: All three of them.

4 BY MR. C. GORDON:

5 Q. The lowest number --

6 A. St. Cloud Hospital, yes.

7 Q. -- is 148 and then there's --

8 A. Coming out, yup, of the distal hose.

9 Q. And then the -- okay. You know what, I --  
10 let me ask you: When it says filter intake,  
11 what is that? What are you measuring there?

12 A. Sure. So the convective-warming unit has an  
13 intake filter that's housed in the bottom end  
14 and it draws air in through that, it goes  
15 through a blower and a heater mechanism and  
16 it passes out through a hose, right, to the  
17 convective-warming blanket.

18 So when we say the intake, we are  
19 holding the particle counter -- when we're  
20 away from the unit, but we have something to  
21 position it on, we're taking counts of what's  
22 going in from the ambient outside air into  
23 the front of the filter.

24 And then the distal hose end is  
25 after it's passed through everything within

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the system.

Q. So what -- what -- the -- the -- the numbers for the filter intake, that's not what -- what's actually coming out of the Bair Hugger, it's what's going into the Bair Hugger --

A. Correct.

Q. -- essentially?

So the measurements of what was -- the particles that were coming out of the -- these Bair Huggers would range from a low of 148 to --

A. Some of these had elevated counts coming out.

Q. Yeah, like there's 29,340, am I reading that right, is that a --

A. Yeah, that looks correct.

Q. Okay.

A. There's a lot of variation as you look across.

Q. If we turn to page 7 of 9, table 4 --

A. Okay.

Q. I'm sorry, wrong one. Table 5 --

A. Okay.

Q. -- page 8 of 9, that's the -- these tables

1 ALBRECHT

2 represent the measurements of the actual  
3 bacteria coming out of the -- of the  
4 Bair Hugger, all nine of these Bair Huggers,  
5 right?

6 A. Correct.

7 Q. And as with the -- just what we looked at  
8 with Regina, same thing at the Alexandria and  
9 St. Cloud Hospitals, these Bair Huggers were  
10 not omitting any bacteria?

11 A. Again, there's no standard to compare that  
12 to, but the counts are not elevated.

13 Q. Okay. Well, in the case of St. Cloud --

14 A. There were none.

15 Q. There were absolutely zero, right?

16 A. Correct.

17 Q. And in the case of the Regina hospital, at  
18 sample start time 0, and an impaction volume  
19 of 1 -- of 1,000, there was 1 in two of them  
20 and --

21 A. Correct.

22 Q. -- 0 in the third -- in the third one and,  
23 then the other two measurements for each of  
24 the -- I'm sorry --

25 A. We also had a control that had a fail, do you

1 ALBRECHT

2 see that? I do want to point that out just  
3 to be --

4 Q. I just caught that. So there's only two  
5 measurements, two active measurements. And  
6 in one of the Bair Huggers, both active  
7 measurements were 0, one of the -- in the two  
8 of the -- the other two, one of the two  
9 active measurements was 0 and the other two  
10 were 1 each at impaction volume of 1,000,  
11 right?

12 A. Correct.

13 Q. So in all three of these hospitals, Hastings,  
14 Alexandria and St. Cloud, you did four basic  
15 measurements, you measured the particles  
16 coming out of the HVAC system --

17 A. Correct.

18 Q. -- you measured the particles coming out of  
19 the Bair Hugger, and the -- and the related  
20 filtration efficiency, particles in,  
21 particles out?

22 A. Yeah, we measured it at two points, correct.

23 Q. You measured or you investigated whether  
24 there were bacteria colony-forming units on  
25 internal surfaces of the Bair Hugger?

1 ALBRECHT

2 A. Correct.

3 Q. And you measured whether there were actual  
4 bacteria, CFUs coming out of the Bair Hugger  
5 in its airstream?

6 A. Correct.

7 Q. And with respect to the Bair Hugger, forget  
8 what -- put aside what you did with the ORs,  
9 those three areas of measurement, particle  
10 passthrough, internal surface bacteria, and  
11 bacteria in the airstream, did you -- is  
12 there any -- any other time that you did all  
13 three of those types of studies of the  
14 Bair Hugger other than these three hospitals?

15 A. I'm unsure. It's been a while. We may have  
16 additional data sources where we did more  
17 studies like that. Do you have any documents  
18 that could help jog my memory on that?

19 Q. Well, I'll go the other way.

20 A. Okay.

21 Q. You did publish some research --

22 A. Correct.

23 Q. -- that you did involving Bair Huggers,  
24 right?

25 A. Yes.

1 ALBRECHT

2 Q. And some of the research you did looked at  
3 filtration efficiency, particles going in,  
4 particles going out, right?

5 A. Yeah, and it was not this data for the  
6 efficiency measures, yes.

7 Q. I understand. But that was one of the  
8 measurements that you published on --

9 A. Correct.

10 Q. -- particles?

11 A. I was a coauthor on a paper that was involved  
12 in that, yes.

13 Q. And one of the things you published on was  
14 bacterial CFUs that you were able to swab or  
15 rinse out of the internal surfaces of the  
16 Bair Hugger, right?

17 A. Correct.

18 Q. But you've never published anything about the  
19 presence or absence of bacteria in the actual  
20 airstream of the Bair Hugger, right?

21 A. I'm unsure. I'd have to look through our  
22 body of publications to confirm that.

23 Q. And as you sit here today, Mr. Albrecht, do  
24 you recall of any discussions after you had  
25 done these -- done these studies and gotten

1 ALBRECHT

2 these results where somebody suggested, you  
3 know, let's not look at the actual bacteria  
4 coming out of the Bair Hugger anymore?

5 MR. B. GORDON: Object to form,  
6 lack of foundation, calls for speculation.

7 THE WITNESS: I'm unsure. There  
8 may be discussions that were had. My  
9 memory -- it's a long time ago, I'm not sure.  
10 If you have something to help me pinpoint  
11 something, I'd be happy to discuss it.

12 BY MR. C. GORDON:

13 Q. Well, you were -- when you were doing the --  
14 the studies on the Bair Hugger, that was at  
15 a -- that was at a time when  
16 Augustine Biomedical & Design was launching  
17 and trying to sell its -- its warming device  
18 in the marketplace, right?

19 MR. B. GORDON: Objection to form,  
20 vague as to time what studies you're  
21 referring to.

22 BY MR. C. GORDON:

23 Q. All the studies you've done on Bair Hugger.

24 A. Yes --

25 Q. I'm -- that's a good point. All the studies

1 ALBRECHT

2 you've done on Bair Hugger when you were  
3 employed by Augustine Biomedical & Design,  
4 not when you were at Arizant.

5 A. There was a market launch and there was a  
6 product on the market at the time these  
7 studies were done, yes.

8 Q. And that product was HotDog, right?

9 A. Correct.

10 Q. Which is a competitive product to the  
11 Bair Hugger, right?

12 A. Correct.

13 Q. And any research that you might have done  
14 that raised any kind of questions about  
15 the -- either the safety or the efficacy of  
16 the Bair Hugger, that kind of research would  
17 have the potential to help out HotDog sales,  
18 wouldn't it?

19 MR. B. GORDON: Objection to form.

20 THE WITNESS: It's a promotional  
21 tool as to sales, yes.

22 BY MR. C. GORDON:

23 Q. And, certainly, you're aware that  
24 Augustine Biomedical and Dr. Augustine has  
25 promoted the HotDog as a safer alternative to



1 ALBRECHT

2 the Bair Hugger, correct?

3 MR. B. GORDON: Object to form.

4 THE WITNESS: Yes.

5 BY MR. C. GORDON:

6 Q. And one of the arguments that has been  
7 advanced by Augustine Biomedical and  
8 Dr. Augustine as to why the HotDog is safer  
9 than the Bair Hugger, is because the  
10 Bair Hugger emits a lot of particles --

11 MR. B. GORDON: Object to form.

12 BY MR. C. GORDON:

13 Q. -- and that doesn't -- there's no -- nothing  
14 that can emit particles from the HotDog  
15 system, right?

16 MR. B. GORDON: Object to form.

17 THE WITNESS: If you could show me  
18 the marketing research you're referring to  
19 for that or the advertisement, I'd feel free  
20 to comment, but that's kind of an open-ended  
21 statement.

22 BY MR. C. GORDON:

23 Q. So just as a general proposition, as you sit  
24 here today, you can't remember any kind of  
25 marketing activities undertaken by

1 ALBRECHT

2 Augustine Biomedical or Dr. Augustine that  
3 suggested that the particles coming out of  
4 the Bair Hugger made it less safe than a  
5 HotDog?

6 MR. B. GORDON: Objection to form,  
7 asked and answered.

8 THE WITNESS: There was marketing.  
9 There was a campaign that was out there, yes.

10 BY MR. C. GORDON:

11 Q. And do you -- do you similarly recall that  
12 one of the arguments advanced for why the  
13 HotDog was safer than the Bair Hugger, or is  
14 safer than the Bair Hugger, is because the  
15 Bair Hugger had -- is a reservoir of bacteria  
16 that can be cultured out of the internal  
17 surfaces?

18 MR. B. GORDON: Objection to form.

19 THE WITNESS: Those are not my  
20 words, that -- that's marketing.

21 BY MR. C. GORDON:

22 Q. And I'm not suggesting they're your words,  
23 I'm just asking if you --

24 A. I'm aware of an ad campaign called  
25 Blowing Air Is Risky that was out there.

1 ALBRECHT

2 Q. And that Blowing Air Is Risky campaign, based  
3 on, in part at least, on research that you  
4 did, argued that Bair Huggers blow out a lot  
5 of particles and have a lot of bacteria  
6 inside them, right?

7 MR. B. GORDON: Object to the  
8 form, mischaracterizes the evidence.

9 THE WITNESS: I would need to see  
10 the specific statement that you'd like me to  
11 comment on, if you have something.

12 BY MR. C. GORDON:

13 Q. Are you aware of any marketing material or  
14 any statement that's ever come out of  
15 Augustine --

16 A. I am, Blowing Air Is Risky, but I'd like to  
17 see the numbers you're looking at.

18 Q. Let me finish. Are you aware of any  
19 statement from Augustine Biomedical or  
20 Dr. Augustine that ever said, We did some  
21 internal studies, and even though there are  
22 bacteria inside the unit, even though  
23 particles blow out of it, we weren't able to  
24 culture any bugs actually coming out of the  
25 Bair Hugger?

1 ALBRECHT

2 MR. B. GORDON: Objection to form,  
3 argumentative, calls for speculation.

4 THE WITNESS: I'm not sure.

5 BY MR. C. GORDON:

6 Q. Well, would you agree that disclosing that  
7 even though there's particles being emitted  
8 and even though there are bacteria inside the  
9 unit, it doesn't blow out any bacteria that  
10 would tend -- that information would tend to  
11 make any claim that the Bair Hugger is  
12 unsafe, less potent?

13 MR. B. GORDON: Objection to form,  
14 misstates the record.

15 THE WITNESS: There are multiple  
16 vectors of how hot air in the operating  
17 theater affects contaminant flow, and  
18 particles out of the unit are one source of  
19 probable issue. The other one is the  
20 disruption of the ventilation system and how  
21 that affects the movement of skin cells  
22 around the operating theater.

23 And so I -- if I'm going to be  
24 honest with you, there's a couple of  
25 different facets to this. It's a very

1 ALBRECHT

2 complicated problem.

3 BY MR. C. GORDON:

4 Q. And -- and we're going to -- we're going to  
5 talk --

6 A. Okay.

7 Q. -- we're going to talk about the  
8 convection --

9 A. Okay.

10 Q. -- currents and the thermal stuff.

11 A. All right.

12 Q. But would -- would -- would -- would you  
13 agree that research that shows there's a lot  
14 of bacteria in the Bair Hugger and a lot of  
15 particles being blown out, if that's all you  
16 know, the implication is that bacteria are  
17 being blown out of the Bair Hugger?

18 MR. B. GORDON: Object to form.

19 THE WITNESS: I think some of the  
20 marketing materials, I'm not sure what exact  
21 claims were made, may have mentioned lines  
22 like that.

23 BY MR. C. GORDON:

24 Q. I'm not even asking if anything was -- was  
25 explicitly said. I'm just saying if -- if

1 ALBRECHT

2 those are the only two pieces of information  
3 that you provide to somebody, bugs inside,  
4 lots of particles blowing out, wouldn't you  
5 think that most people would think, well,  
6 then there's probably bacteria being blown  
7 out too?

8 A. I don't know. That's speculation on my part  
9 to make any answer to that.

10 Q. Sure. Other than these three internal  
11 studies that you never published that  
12 actually looked at bugs being blown out --

13 A. Okay.

14 Q. -- of the Bair Hugger, and you found  
15 basically none --

16 MR. B. GORDON: Object -- object  
17 to the characterization.

18 THE WITNESS: With the small  
19 sample of units we were unable to detect  
20 anything.

21 BY MR. C. GORDON:

22 Q. Did you ever do a large sample where you  
23 tried to detect bugs coming out of the  
24 Bair Hugger?

25 A. I would like to review the research studies

1 ALBRECHT

2 so I can see what sources. There's a couple  
3 of them that would help me remember what we  
4 did. So there's an American Journal of  
5 Infection Control article that I think would  
6 be helpful if I could look through that.

7 Q. Sure.

8 MR. B. GORDON: And he's asked for  
9 those a couple of times, Corey.

10 MR. C. GORDON: Yeah. We'll --  
11 we'll -- we'll take a break and we'll --  
12 we'll put all your --

13 MS. ZIMMERMAN: Counsel --

14 MR. C. GORDON: -- your published  
15 studies on the record.

16 MR. B. GORDON: We'll give them to  
17 him on the break. We've got to take a break.

18 MR. C. GORDON: My timing is  
19 perfect.

20 THE VIDEOGRAPHER: We're going off  
21 the record at 11:11 a.m.

22 (Whereupon, a brief recess  
23 was taken.)

24 THE VIDEOGRAPHER: This is video  
25 number 2 in the deposition of Mark Albrecht.

1 ALBRECHT

2 Today is October 7th, 2016. We're going back  
3 on the record at 11:42 a.m.

4 (Whereupon, Exhibit 4, Exhibit 5,  
5 Exhibit 6, Exhibit 7, Exhibit 8  
6 and Exhibit 9 was marked for  
7 identification.)

8 BY MR. C. GORDON:

9 Q. Mr. Albrecht, I've given you several  
10 exhibits, and I just want to go through them  
11 for the record. Exhibit 4 is a 2009 article,  
12 Forced Air Warming: A Source of Airborne  
13 Contamination in the Operating Room, by  
14 Albrecht, Gauthier and Leaper, correct?

15 A. Correct.

16 Q. Exhibit 5 is a 2013 article, Forced-Air  
17 Warming Design: Evaluation of Intake  
18 Filtration, Internal Microbial Buildup, and  
19 Airborne Contamination Emissions, by Reed,  
20 Kimberger -- Kimberger, McGovern and  
21 Albrecht, correct?

22 A. Correct.

23 Q. Exhibit 6 is a 2011 publication, Forced-Air  
24 Warming Blowers: An Evaluation of Filtration  
25 Adequacy and Airborne Contamination Emissions



1 ALBRECHT

2 in the operating room, by Albrecht, Gauthier,  
3 Belani, Litchy and Leaper, correct?

4 A. Yup. Correct.

5 Q. And number -- Exhibit 7 is a 2013  
6 publication, Patient Warming, Excess Heat,  
7 the Effects on Operating -- Orthopedic  
8 Operating Room Ventilation Performance, by  
9 Belani, Albrecht, McGovern, Reed and  
10 Nachtsheim, correct?

11 A. Correct.

12 Q. Number 8 is a 2011 publication, Forced-Air  
13 Warming and Ultra-clean Ventilation Do Not  
14 Mix, An Investigation of Theater Ventilation  
15 in Patient Warming and Joint Replacement  
16 Infection in Orthopaedics, by McGovern,  
17 Albrecht, Belani, Nachtsheim, Partington,  
18 Carluke, and Reed, correct?

19 A. Correct.

20 Q. And Exhibit 9 is a 2012 publication, Effect  
21 of Forced-Air Warming on the Performance of  
22 Operating Theater Laminar Flow Ventilation,  
23 by Dasari, Albrecht and Harper, correct?

24 A. Correct.

25 Q. The -- so you are a coauthor on all six of

1 ALBRECHT

2 these studies, published studies from  
3 Exhibits 4 through 9, correct?

4 A. Correct.

5 Q. Are there any other published studies of  
6 which -- on which you appear as a coauthor  
7 that in any way involve the Bair Hugger  
8 specifically or forced-air warming generally  
9 other than these six?

10 A. I don't think so, but I would have to do a  
11 literature search to make sure.

12 Q. Okay. How would you go about doing that  
13 literature search?

14 A. We'd have to go through PubMed and look  
15 through for the articles and see what comes  
16 up. I could also look on a resume if we had  
17 one handy.

18 Q. That's right, my -- I promised you a resume.

19 A. I think they're complete on there, but you  
20 never know.

21 Q. No, and -- and -- and we want to be complete,  
22 that's fair.

23 I want to see if we can kind of  
24 create baskets to put these different studies  
25 in. One basket would be a study that

1 ALBRECHT

2 actually looks at infection rates.

3 A. Okay.

4 Q. Am I correct that the only study that has  
5 that as a component is Exhibit 8?

6 MR. B. GORDON: I'll object to the  
7 form as being overbroad. It might take him  
8 time to know for sure.

9 MR. C. GORDON: No, I want him to  
10 take the time.

11 THE WITNESS: (Reviews document.)  
12 Yeah, so this study does have observational  
13 infection data. That's not a properly  
14 controlled trial.

15 This does not, (indicating).

16 (Reviews documents.)

17 MR. B. GORDON: I don't think our  
18 feed is updating. Okay, it is. I'm sorry.  
19 We're good.

20 THE WITNESS: That's not,  
21 (indicating).

22 This one shouldn't, (indicating).

23 That is the only one, yes.

24 MR. C. GORDON: Okay.

25 BY MR. C. GORDON:

1 ALBRECHT

2 Q. So we'll call that an infection rate basket,  
3 if you will.

4 And then some of these studies  
5 address issues related to the -- the impact  
6 that the Bair Hugger may have on operating  
7 room airflow.

8 A. Yes.

9 Q. Okay.

10 A. They do.

11 Q. So I'll -- I'll call that, just for  
12 shorthand, my airflow basket.

13 A. Sure.

14 Q. And Exhibit 8, which has an infection rate  
15 component to it, also has an airflow  
16 component to it, correct?

17 A. Yes, it does.

18 Q. And Exhibit 9 --

19 A. Yup.

20 Q. -- would be an airflow study, right?

21 A. I agree.

22 Q. And Exhibit 7 would be an airflow study,  
23 right?

24 A. Yes.

25 Q. And then the third basket, I'll actually use

1 ALBRECHT

2 your phrase, the crud and bug.

3 A. Is that my phrase?

4 Q. Do you remember using that phrase?

5 A. I don't know. Maybe I did.

6 Q. Okay.

7 MR. B. GORDON: I don't remember  
8 that.

9 THE WITNESS: I think that's  
10 Scott Augustine's phrase.

11 MR. B. GORDON: Did I step out or  
12 something like that? Accordingly, I object  
13 to the form of that question.

14 MR. C. GORDON: I'm sorry.

15 MR. B. GORDON: I object to the  
16 form of the "crud and bug" to the extent  
17 it --

18 MR. C. GORDON: Well, if he  
19 doesn't remember --

20 MR. B. GORDON: --  
21 mischaracterizes his testimony.

22 THE WITNESS: I may have. Do you  
23 have an e-mail with that?

24 MR. C. GORDON: Yeah, but it's no  
25 big deal.

1 ALBRECHT

2 BY MR. C. GORDON:

3 Q. Studies that look at the Bair Hugger itself  
4 as a potential source of air contamination.

5 A. Okay.

6 Q. Okay?

7 A. Yup.

8 Q. And that would be 4, 5 and 6, right?

9 A. Yup.

10 Q. So the studies that we spent a good portion  
11 of the morning looking at in the hospitals in  
12 Hastings and Alexandria and St. Cloud,  
13 those -- none of those had an infection rate  
14 component to it, correct?

15 A. They did not.

16 Q. And none of those had an airflow disruption  
17 aspect to it, correct?

18 A. Let me look carefully here.

19 (Reviews documents.)

20 No, these were filtration based.

21 Q. Okay. And the -- let's talk about the  
22 filtration-based study, you referred to it as  
23 filtration based. There were three basic  
24 components to the studies you did at those --  
25 those Minnesota hospitals looking at, one,

1 ALBRECHT

2 particle emissions both in incoming and  
3 outgoing and --

4 A. Correct.

5 Q. -- calculating filtration efficiency, but  
6 still those were particles, right?

7 A. Yup.

8 Q. Number two, you looked at internal surface  
9 bacteria by swabbing --

10 A. Correct.

11 Q. -- and rinsing, right?

12 A. Yup.

13 Q. And number 3, you looked at bacteria in the  
14 airstream?

15 A. On some of the units that appear in these  
16 studies, not all.

17 Q. Some of the units at those three hospitals in  
18 Minnesota?

19 A. Yes.

20 Q. Okay. And in those three Minnesota hospitals  
21 you -- you found particle emissions with  
22 vary -- varying -- varying efficiency of the  
23 filter, you found internal surface  
24 contamination in many of the units, right?

25 A. Correct.

1 ALBRECHT

2 Q. But you didn't find any bacteria blowing out  
3 of the units?

4 A. When sampled at rest. So these studies of  
5 the impaction weren't run with the  
6 Bair Hugger in a working operating theater  
7 with a lot of skin cell load in the air that  
8 could have been pushed in and sucked through,  
9 and so we had very inconclusive results with  
10 the colony-forming unit counts, because  
11 there's a lot of mechanics that have to  
12 happen to make that go when it came to the  
13 airborne.

14 Q. Okay. So of the -- the three studies that  
15 looked at the Bair Hugger as a possible  
16 source, Exhibits 4, 5 and 6, all four of them  
17 looked at particle emissions, right?

18 A. They did.

19 Q. And filtration efficiency based on particles  
20 entering and particles exiting, right?

21 A. Yup.

22 Q. All three of these studies looked at internal  
23 surface contamination based on swabbing and  
24 rinsing, right?

25 A. Correct.



1 ALBRECHT

2 Q. But none of them looked at actual bacteria in  
3 the airstream, correct?

4 A. Yes, because these were done -- most of the  
5 these studies, the intent was to look at the  
6 theaters at rest and see what was in the  
7 units, and air sampling results were  
8 inconclusive, as you can see here.

9 For example, the impaction device,  
10 you need a working theater to look at  
11 colony -- colony-forming units with viable  
12 bacteria entering and passing. And so it was  
13 a more complicated set up to do the full air  
14 impaction study and we would have needed to  
15 have some kind of surgical component going  
16 on.

17 Q. Well, do any of these studies involve a  
18 simulated surgical activity?

19 A. These here do, (indicating).

20 Q. You're talking about 7, 8 and 9?

21 A. Yup.

22 Q. But not --

23 A. Let me look --

24 Q. -- 4, 5 and 6?

25 A. Let me look through carefully.

1 ALBRECHT

2 (Reviews documents.)

3 I believe this was all at rest  
4 testing, yes.

5 Q. Which ones were at rest testing?

6 A. Let me look through them all for you. If you  
7 want a very specific answer, let me sort for  
8 that, please.

9 Q. Please.

10 A. (Reviews documents.) This one, (indicating),  
11 I believe was all at rest testing.

12 Q. You're pointing to Exhibit 4?

13 A. Yup. Let's look at Exhibit 5 here.

14 (Reviews documents.) This one looks at rest,  
15 so that's Exhibit 5. (Reviews documents.)

16 After hours once again, so, yeah. (Reviews  
17 documents.) These were all at rest.

18 Q. And in none of these studies do you reference  
19 any research that demonstrated no bugs in the  
20 air?

21 MR. B. GORDON: Object to form.

22 THE WITNESS: We felt to do that  
23 we would need to have some kind of simulated  
24 surgery going on and it couldn't be done at  
25 rest. We thought instead to look at some of

1 ALBRECHT

2 the more fundamental engineering components  
3 you could measure first, such as the filter,  
4 which is easily quantifiable and doesn't have  
5 a lot of additional sources to go on, such as  
6 bugs being released by people in taking to  
7 the stream, things like that that have to  
8 happen for the mechanism to occur, so we  
9 started with the first engineering  
10 principles.

11 And so, no, we did not present the  
12 impaction data in these studies, because we  
13 weren't sure to make of it because it was  
14 done at rest and it did not have the load  
15 component that would make it appropriate.

16 BY MR. C. GORDON:

17 Q. Well, the -- the particulate emissions was  
18 done at rest too, wasn't it?

19 A. Yup, and the thinking is a little different  
20 on that, that a unit can collect things over  
21 time inside of it and we were looking for --  
22 I'm sorry, the filtration piece or the swab  
23 piece internally, which would you like to  
24 talk about?

25 Q. Let's go to Exhibit 4.

1 ALBRECHT

2 A. Okay.

3 Q. In the second paragraph it says, "We measured  
4 the emission of viable and nonviable forms of  
5 airborne contamination from an arbitrary  
6 selection of FAW blowers in the operating  
7 room"; do you see that?

8 A. Where?

9 Q. Second paragraph.

10 A. Okay.

11 Q. How did you measure the viable emissions?

12 A. Through means of a particle counter, and  
13 inferring if it's of a certain size of  
14 particulate, that it could be viable.

15 Q. You had data from those three hospitals that  
16 showed that even when you had particulate  
17 emissions of various sizes, a wide range of  
18 sizes, you couldn't get any bugs to culture  
19 out on a -- on an agar plate, right?

20 MR. B. GORDON: Object to form.

21 THE WITNESS: We did get some.

22 There were colony counts coming out of the  
23 units, just low numbers.

24 BY MR. C. GORDON:

25 Q. Well, you can't get too much lower than 1,

1 ALBRECHT

2 right?

3 A. No, you cannot.

4 Q. And almost all of the measurements were 0,  
5 right?

6 A. We can look at that statistically, if you'd  
7 like.

8 Q. Well, there were a couple that said -- there  
9 were a couple that were 1, and every other  
10 one was 0, right, and a control was 1 in one  
11 instance, right?

12 MR. B. GORDON: You're talking  
13 about for the hospitals?

14 MR. C. GORDON: Yup.

15 THE WITNESS: So we do have that  
16 in the table, let's look at that.

17 BY MR. C. GORDON:

18 Q. You have that in the table that no one  
19 outside of August Biomedical saw, right?

20 MR. B. GORDON: Object to form,  
21 argumentative, move to strike.

22 MR. C. GORDON: Well, yeah, I'll  
23 withdraw that.

24 BY MR. C. GORDON:

25 Q. Did anyone ever -- did anyone within the

1 ALBRECHT

2 Augustine Biomedical ever share the table  
3 that showed almost all zeros with anyone  
4 outside of Augustine Biomedical?

5 MR. B. GORDON: Objection to form.  
6 It was asked and answered earlier.

7 THE WITNESS: The coauthors  
8 reviewed the data, so David Leaper and  
9 Robert Gauthier would have had a chance to  
10 look at this. I don't know if they saw that  
11 report as part of the body of evidence, or I  
12 should say part of the data set.

13 BY MR. C. GORDON:

14 Q. Under, "Sampling Procedures," on Exhibit 4,  
15 it says, "FAW blowers from hospitals in the  
16 vicinity of Minneapolis and St. Paul were  
17 sampled after hours," et cetera, et cetera.

18 Did -- does -- do any -- are any of  
19 the data in Exhibit 4 based on any of those  
20 three hospitals that we spent the morning  
21 looking at, Hastings, St. Cloud and --

22 MR. B. GORDON: Alexandria.

23 BY MR. C. GORDON:

24 Q. -- Alexandria?

25 A. I believe -- yes, there should be. Let me

1 ALBRECHT

2 look carefully, but I would imagine.

3 (Reviews documents.) Let me look at the  
4 methods very carefully. (Reviews documents.)

5 Yes, I would expect those hospitals  
6 to be a part of this.

7 Q. So it's your recollection that Dr. Leaper and  
8 Dr. Gauthier both would have had access to  
9 the information that showed that of the three  
10 Bair Hugger units sampled from St. Cloud  
11 Hospital, not a single one cultured out a  
12 single CFU; and the three samples -- or three  
13 Bair Huggers sampled at Alexandria, of the  
14 six measurements, two of the measurements had  
15 one CFU and the other four were zeros; and at  
16 the Regina center, of the three units tested,  
17 there were nine measurements, and one unit  
18 had all zeros, one unit had one -- one CFU on  
19 one measurement and zero CFUs on the other  
20 two, at the same time the control had one CFU  
21 measured; and the third unit had one -- one  
22 CFU measured at the start and two zeros?

23 MR. B. GORDON: Object to form,  
24 compound, misstates the record.

25 THE WITNESS: If I recall

1 ALBRECHT

2 correctly, it was a while ago, we had a  
3 discussion about the impaction results and  
4 felt that the fact that we weren't doing the  
5 operating theater under load makes those  
6 difficult to interpret.

7 BY MR. C. GORDON:

8 Q. Is there anywhere in Exhibit 4 where you  
9 alerted the reader to the fact that you had  
10 had these results from the actual attempt to  
11 measure viable airborne contamination?

12 A. I do not believe so, and we didn't think it  
13 was relevant because it wasn't under load,  
14 but let me look. (Reviews documents.)

15 No, we do not reference that in the  
16 discussion.

17 Q. But you had a discussion with your coauthors  
18 about the fact that you had attempted to --  
19 to actually culture out bacteria from the  
20 airstream of the various Bair Huggers that  
21 you sampled and you found little or no growth  
22 occurred on the agar plates?

23 A. I don't recall if that discussion was  
24 directly had in that manner with the  
25 coauthors. It was a long time ago. I know



1 ALBRECHT

2 internally we had some discussions in the  
3 company about thinking through this. And the  
4 fact that the OR was at rest versus under  
5 load was our reason for saying, hey, we can't  
6 go this far along in the chain to recording  
7 bacteria, we need to start with some of the  
8 further up fundamentals, such as what's the  
9 quality of the filter, are things building up  
10 inside the unit, what's coming out, and we  
11 were uncertain that this kind of sampling was  
12 reflective of what would happen under normal  
13 operating conditions in the theater.

14 Q. Could be, maybe it wasn't, right?

15 MR. B. GORDON: Object to form.

16 THE WITNESS: I'm uncertain if we  
17 talked about this.

18 BY MR. C. GORDON:

19 Q. No, I'm sorry, whether the -- your earlier  
20 measurements where you found little or no  
21 growth in the actual airstream for the  
22 Bair Huggers, you're not -- you're saying you  
23 weren't sure whether that was or was not  
24 representative of what actually occurs in the  
25 operating room?

1 ALBRECHT

2 MR. B. GORDON: Object to form,  
3 misstates the evidence, asked and answered.

4 THE WITNESS: Can you ask that in  
5 a different way?

6 BY MR. C. GORDON:

7 Q. Well, you said you had a discussion about how  
8 this was not under load so that didn't  
9 necessarily represent what was actually  
10 happening in an OR?

11 A. We were unsure how to interpret this result,  
12 so we chose to study the things that were  
13 easier to define.

14 Q. Okay. And you had the -- did you have that  
15 discussion with Scott Augustine?

16 A. I believe we did at some point.

17 Q. And when you say the things that are easier  
18 to find, you found particles --

19 A. Easier to study, not to find.

20 Q. Easier to study.

21 A. To quantify.

22 Q. To quantify.

23 A. Because this is an operating room at rest,  
24 there are a lot of factors at play that make  
25 it nonrepresentative, so we wanted to

1 ALBRECHT

2 quantify the things we felt we could in a  
3 rest theater.

4 Q. And one of the things you knew you could  
5 quantify was particle emissions from the --  
6 from a Bair Hugger, right?

7 A. Yes.

8 Q. And one of the things you knew you could  
9 quantify were bacteria inside adhering to the  
10 surfaces, right?

11 A. Correct.

12 Q. And one of the things you knew you couldn't  
13 quantify were actual bugs, bacteria actually  
14 coming out of the Bair Hugger?

15 MR. B. GORDON: Objection to form,  
16 misstates his testimony. He said it wasn't  
17 under load. He's answered that six times.

18 THE WITNESS: We're unsure of the  
19 proper way to quantify that in the theater at  
20 rest that translates to one that would be  
21 under load.

22 BY MR. C. GORDON:

23 Q. In Exhibit 4 you said you measured emission  
24 of viable forms of airborne contamination,  
25 but you really didn't measure it, right?

1 ALBRECHT

2 A. We inferred.

3 Q. Do you say anywhere in Exhibit 4 that your  
4 measurements of the emission of viable  
5 airborne contamination was inferred?

6 A. "Common operating airborne microbes in the .5  
7 to 5 micron science range include unclumped  
8 bacteria and fungi. Nonviable sources may  
9 have included particles generating from  
10 moving components, which can become buoyant  
11 airborne carriers of microbes. Additionally,  
12 CFUs detected by rinsing were lower than CFUs  
13 detected by swabbing." Okay. Let's see  
14 here. (Reviews document.)

15 "The presence of microbes on air  
16 passed surfaces in 94 percent of the blowers  
17 suggest that a viable component could be  
18 present in the emitted contaminants."

19 MR. B. GORDON: That sounds like  
20 an inference to me.

21 THE WITNESS: And the inference in  
22 context is, "Common operating room airborne  
23 microbes in the .5 to 5 micron science range  
24 include unclumped bacteria and fungi."

25 BY MR. C. GORDON:

1 ALBRECHT

2 Q. And you didn't feel it was important to tell  
3 the readers of this that you actually had  
4 tried to measure the bacteria and found, with  
5 the methodology you were using, little or no  
6 actual bacterial omissions?

7 MR. B. GORDON: Object to form,  
8 argumentative, misstates the evidence.

9 THE WITNESS: We decided to scope  
10 this research around the pieces that we had  
11 complete coverage on and felt that we could  
12 more accurately measure.

13 BY MR. C. GORDON:

14 Q. And --

15 THE WITNESS: To do that  
16 accurately, we thought we needed something  
17 that was not at rest.

18 BY MR. C. GORDON:

19 Q. You had seen the data from the operating  
20 rooms where there were thousands and  
21 thousands of particles being emitted, but  
22 none -- none -- no bacteria being cultured,  
23 right?

24 A. Atmospheric particles, which is a different  
25 source than what is likely to be resident in

1 ALBRECHT

2 a Bair Hugger filter that is in the operating  
3 theater where there's a large quantity of  
4 skin cells.

5 Q. What's your basis for saying that it's --  
6 that it's different?

7 A. So the filtration system in a hospital  
8 removes a lot of atmospheric contaminants,  
9 pollens, things like that that are coming in  
10 from the outside. Once that clean air is  
11 into the hospital, there's a lot of research  
12 suggesting that the bulk of the dust you see  
13 in airborne contaminants actually in the  
14 theater that the Bair Hugger would be  
15 operating are shed skin cells that have  
16 fomites on them, you know, bacteria, and so  
17 the particle concentration coming out of the  
18 two is hard to relate to one another. And  
19 the particle counts were much lower out of  
20 the Bair Huggers than they were out of the  
21 plenum, in a lot of these cases.

22 Q. What's a fomite?

23 A. It's an airborne carrier of bacteria, like a  
24 floating skin cell.

25 Q. How big are fomites?

ALBRECHT

A. The fomites themselves is large, 20 to 30 microns in size, but they can break off and have bacteria fall from them, they can have airborne bacteria floating around without a fomite, but skin cells tend to be larger.

Q. So you're saying that the little or no bacterial growth that you got when you actually tried to measure what was coming out of the -- the Bair Hugger, that -- that was inconclusive because it wasn't -- there wasn't air --

A. There wasn't a concurrent challenge --

Q. Let me finish my -- there wasn't a concurrent challenge from what was coming from what could be in the operating room?

A. Yes.

Q. But you measured bacteria that was inside the Bair Hugger, right?

A. Yup, that might have been adhered to the surface, yes.

Q. Right. And -- and you found bacteria that had adhered to the surface?

A. Suggesting that bacteria does penetrate the filter and can be flowing through the unit.

1 ALBRECHT

2 Q. But you couldn't find any?

3 A. When sampled at rest, we did not find.

4 Q. Okay. But what's the rationale for doing, in  
5 fact, several articles showing bacterial  
6 contamination in internal surfaces that could  
7 only be dislodged by swabbing or rinsing?

8 MR. B. GORDON: Objection; asked  
9 and answered.

10 THE WITNESS: They could be  
11 dislodged by other factors too.

12 MR. C. GORDON: Okay.

13 BY MR. C. GORDON:

14 Q. Well, if your concern -- if your -- if your  
15 theory is that bacteria inside the -- the  
16 Bair Hugger could somehow become mobilized  
17 and enter the airstream, that would be true  
18 whether it's at rest or there's other stuff  
19 coming in, right?

20 MR. B. GORDON: Objection to form,  
21 argumentative.

22 THE WITNESS: It's possible, yes,  
23 that is one source.

24 BY MR. C. GORDON:

25 Q. Do you think anyone reading this article



1 ALBRECHT

2 would think, well, gees, if there's bacteria  
3 on the inside and there's particles coming  
4 out, maybe there's -- those particles contain  
5 bacteria?

6 MR. B. GORDON: Objection; calls  
7 for speculation as to what people think.

8 THE WITNESS: Readers are going to  
9 infer what they're going to infer.

10 BY MR. C. GORDON:

11 Q. Well, isn't that what you intended them to  
12 infer?

13 A. No.

14 Q. Your -- the title of this is, "Forced-Air  
15 Warming: A Source of Airborne Contamination  
16 in the Operating Room?"

17 A. Yes. There's a large number of particles  
18 coming out and we want to pose the question  
19 what are they and spur on further research.  
20 That's kind of the point of an article like  
21 this, is to introduce a topic to get the next  
22 phase going.

23 Q. Is there somewhere where you -- where you say  
24 we need to spur on further research and see  
25 if what's coming out of the Bair Hugger is

1 ALBRECHT

2 actually -- actually contains bacteria?

3 MR. B. GORDON: Objection to form,  
4 argumentative.

5 THE WITNESS: Based on the  
6 findings of other authors that have looked at  
7 this too, we highlight essentially two  
8 components that the filters should be looked  
9 at and the internal paths should be able to  
10 be decontaminated, those are the major  
11 conclusions that are here.

12 BY MR. C. GORDON:

13 Q. If there are no bugs actually blowing out of  
14 the Bair Hugger --

15 A. We don't have conclusive data to know that,  
16 this isn't enough.

17 Q. Is there anywhere you suggest that you have  
18 inconclusive data on what actually comes out  
19 of the Bair Hugger?

20 A. We specify the particulate distribution  
21 coming out and we specify the size of  
22 microbes coming out.

23 Q. But nowhere do you say we also have  
24 inconclusive data that suggests that bacteria  
25 actually don't come out of the Bair Hugger,

1 ALBRECHT

2 but more research is needed?

3 MR. B. GORDON: Objection to form.

4 He explained that several times about the --

5 THE WITNESS: We did not include  
6 that. We did not want to compare what we  
7 thought needed to be studied in an active  
8 theater to a study that was done at rest.

9 BY MR. C. GORDON:

10 Q. And you did at least two more studies, 5 and  
11 6, where you did basically the same thing?

12 MR. B. GORDON: Objection to the  
13 characterization.

14 THE WITNESS: No, these were very  
15 different.

16 BY MR. C. GORDON:

17 Q. How were they different?

18 MR. B. GORDON: Objection to form,  
19 overbroad.

20 THE WITNESS: One of the studies  
21 did a quantitative filter rating by an  
22 independent lab on what the true efficiency  
23 was of the intake filters of two popular  
24 Bair Hugger models, the 505 and the 750, and  
25 we wanted a formal efficiency rating in

1 ALBRECHT

2 conjunction with looking at what is coming  
3 out of these units to better understand how  
4 the internal surfaces could be getting  
5 contaminated.

6 BY MR. C. GORDON:

7 Q. Filtration efficiency doesn't matter if no  
8 bugs get out of the Bair Hugger, right?

9 A. We don't know that.

10 Q. If that were -- if that were the case, if --  
11 if bugs don't escape the Bair Hugger, then  
12 the filter efficiency doesn't matter, right?

13 MR. B. GORDON: Objection to  
14 the --

15 BY MR. C. GORDON:

16 Q. From a -- from a bacteria standpoint. It may  
17 matter for protecting the motor, the  
18 efficiency of the unit.

19 MR. B. GORDON: Objection to form,  
20 mischaracterizes the evidence, calls for  
21 speculation.

22 THE WITNESS: Say that clearly one  
23 more time.

24 BY MR. C. GORDON:

25 Q. If it were a fact that your inconclusive

1 ALBRECHT

2 results really were conclusive and --

3 A. But that's not a fact.

4 Q. I understand. I'm asking you, though, if  
5 somebody else were to do what you did  
6 inconclusively and demonstrate conclusively  
7 that bugs don't come out of the Bair Hugger,  
8 the -- the efficiency of the filter is  
9 irrelevant, right?

10 MR. B. GORDON: Objection to form,  
11 improper hypothetical, calls for speculation.

12 THE WITNESS: So there is an  
13 article, Number 21, Avidan, Jones and Ing,  
14 Convection Blowers, Not Just Hot Air,  
15 published in Anesthesia in 1997 that did find  
16 airborne bacteria coming out of the blowers.

17 MR. C. GORDON: Right.

18 BY MR. C. GORDON:

19 Q. They -- they blew the -- they blew the  
20 airstream onto agar plates and cultured out  
21 some CFUs, correct?

22 A. Correct.

23 Q. Then they put the -- the hose into the  
24 blanket, attached it to the blanket as it is  
25 supposed to be --

1 ALBRECHT

2 A. They did.

3 Q. -- and they got zero, right?

4 A. In a small study in a limited number of  
5 units.

6 Q. They got zero, right?

7 A. In that study, yes.

8 Q. Okay. And you got zero?

9 A. No, not true --

10 MR. B. GORDON: Objection to  
11 mischaracterization of the evidence, asked  
12 and answered.

13 THE WITNESS: -- there were a  
14 number of colony-forming units that were  
15 detected airborne with the impaction device.

16 BY MR. C. GORDON:

17 Q. In the majority of the -- in almost all of  
18 the units there was zero --

19 A. The data states that two out of nine had a  
20 colony-forming unit detected -- sorry, two  
21 out of three had a colony-forming unit  
22 detected in the experiments.

23 Q. And one of those the control also had one  
24 colony-forming unit in it, right?

25 A. It did, in one study. I'm just looking

ALBRECHT

through this if you want clear answers.

Q. In Exhibit 4 you say, in the third column on the front page just above, "Materials," and, "Methods," "Therefore, in this study we investigated the emission of both viable and nonviable forms of airborne contamination." What did you do to investigate the emission of viable forms of airborne contamination?

A. In this study and what was done here?

Q. Yeah.

A. We used a particle counter and we swabbed the internal surfaces of the unit, and those are the two points of data that comprised the study.

Q. That was your investigation of actual emission of viable -- viable forms of airborne contamination?

A. Yes.

Q. Okay. And this was based, in part, on research where you actually did do something to investigate the emission of viable forms of bacteria, which is to measure CFUs in the airstream?

A. We had an impaction apparatus that we

ALBRECHT

measured at rest, yes.

Q. And nowhere is that disclosed in Exhibit 4?

A. I do not see it in the paper, no. We felt it was out of scope.

Q. And nowhere is that mentioned in Exhibit 5 or Exhibit 6?

A. No, it is not mentioned.

Q. So you just -- you did these studies to let the -- let the readers know that, hey, these filters aren't very efficient and that there's bacteria inside the Bair Hugger?

A. That is not my motive for doing the studies, no.

Q. What was your motive?

A. To look at the engineering principles and ask the question is the filter Hepa, what is the filter efficiency, because no one has looked at it, are contaminants inside these units building up, can they be cleaned, is there a way to access those internal surfaces that, you know, are inside the blower and decontaminates them, is there a reason to. So we're looking at items like that to start.

Q. Why? What's the concern?



1 ALBRECHT

2 A. The concern is that you could have viable  
3 contaminants coming out of the unit and we  
4 don't have enough evidence to say yes or no  
5 on that completely.

6 Q. But you didn't disclose any of the --  
7 anywhere the inclusive evidence that you had  
8 on the only thing that really matters?

9 MR. B. GORDON: Objection; asked  
10 and answered at least three times, maybe  
11 four. You know, if you asked every question  
12 that you don't like the answer to four times,  
13 we'll be here four times as long, Corey.  
14 It's not fair.

15 MR. C. GORDON: Your objection is  
16 noted and --

17 MR. B. GORDON: Well, it's not  
18 fair --

19 MR. C. GORDON: -- I think it  
20 violates the --

21 MR. B. GORDON: You're scowling at  
22 him and you're --

23 MR. C. GORDON: It violates the  
24 order for nonspeaking objections.

25 MR. B. GORDON: -- hostile to him,

1 ALBRECHT

2 and I don't understand why --

3 MR. C. GORDON: I'm not scowling.

4 MR. B. GORDON: -- he's a fact  
5 witness.

6 We're going to get a video camera on  
7 you next time. You have been scowling at  
8 him.

9 MR. C. GORDON: Okay.

10 Strike counsel's comments.

11 MR. ASSAAD: You have to move to  
12 strike. You have to strike it.

13 MR. C. GORDON: Move to strike  
14 counsel's comments.

15 MR. B. GORDON: Move all you want,  
16 just be nice to him and move on.

17 MR. C. GORDON: And -- and -- and,  
18 you know, the rule is one lawyer talks and  
19 the rules also prohibit speaking objections.

20 Could you read my question back from  
21 a couple years ago.

22 (Whereupon, the last question  
23 was read by the court reporter.)

24 MR. B. GORDON: Same objection.

25 THE WITNESS: We didn't study a

1 ALBRECHT

2 theater -- the theater we studied was at  
3 rest, we felt that that wasn't appropriate to  
4 include. We didn't think it was  
5 representative of the issue that we're  
6 measuring.

7 BY MR. C. GORDON:

8 Q. Did you ever suggest to anyone that they  
9 conduct a study with a theater not at rest  
10 and see if there's actually airborne bacteria  
11 coming out of the -- the Bair Hugger?

12 MR. B. GORDON: Objection; asked  
13 and answered several times.

14 THE WITNESS: We would love other  
15 people to do those studies.

16 BY MR. C. GORDON:

17 Q. Did you ever suggest it to anyone that they  
18 do that kind of a study?

19 A. In the body of the text here, no.

20 Q. Any -- any time in your entire life?

21 A. No, I have not talked to researchers to do  
22 that. Instead, we chose to go after the  
23 things that were simpler and could be  
24 quantified from first principles to kind of  
25 start at the bottom of the pyramid; filter,

1 ALBRECHT

2 filter efficiency, are things passing through  
3 the filter before we try and connect all the  
4 elements together and say, hey, are there  
5 bugs coming out of the airstream.

6 Q. Did you ever suggest to anyone that they try  
7 to connect those things that you looked at  
8 to -- to what actually matters, bacteria  
9 coming out of the --

10 A. Yes, we've had lots of discussions. We had  
11 them with the orthopedists as we designed  
12 these other studies, you know, how do we go  
13 about answering the question is there a risk.  
14 You know, one vector of contamination is  
15 what's coming out of the unit, that's a  
16 possible source we have to look at. There  
17 are other vectors too that are examined.

18 Q. We're going to talk about those other  
19 vectors. But I -- I -- so did anyone have  
20 these discussions --

21 MR. B. GORDON: Object to the  
22 sidebar.

23 BY MR. C. GORDON:

24 Q. Did anyone have these discussions that you  
25 had these discussions with suggest any kind

1 ALBRECHT

2 of study or methodology for actually looking  
3 at connecting these dots and seeing if any of  
4 the bacteria that's -- you're finding inside  
5 and the particles that are coming out  
6 actually contained bacteria?

7 A. I'm not sure. We kind of started down the  
8 path and we looked at the filter first, and  
9 that's what these studies are about, then we  
10 looked at the next thing to answer the  
11 question is there buildup inside. We wanted  
12 to see if that buildup was biological in  
13 origin, because there are decontamination  
14 issues that are present if you can't clean  
15 surfaces. And I don't know if we got to that  
16 point before we started chasing other  
17 butterflies on this.

18 Q. Take a look at Exhibit 8.

19 A. Okay.

20 Q. That's the -- the one study that you agreed  
21 had a component of it that actually looked at  
22 infection rates.

23 A. Observational.

24 MR. B. GORDON: Object to the  
25 characterization by counsel.

1 ALBRECHT

2 BY MR. C. GORDON:

3 Q. What do you mean by observational?

4 A. Well, this isn't a randomized clinical trial  
5 that was conducted here. Let me read the  
6 point in the discussion I think around that.

7 MR. B. GORDON: For the record, I  
8 want the record to reflect there are  
9 highlights in this document that I don't know  
10 where they came from, I don't think they're  
11 the witness's.

12 MR. C. GORDON: Yeah, your point  
13 is well-taken. Maybe we can -- we'll find a  
14 clean copy.

15 MR. B. GORDON: And, actually,  
16 there's some writing in here too, page 1542.

17 MR. C. GORDON: Yeah, I don't know  
18 where that came from but we'll just...

19 THE WITNESS: Yeah, sorry, I lost  
20 my track here. Go ahead and repeat what  
21 we're -- so you wanted a comment about the  
22 observational versus --

23 BY MR. C. GORDON:

24 Q. What -- what -- what do you mean by an  
25 observational study? You said it was not a

ALBRECHT

randomized clinical trial.

A. Yeah. There wasn't a control group in place at the same time where you give half a device to one group and half to the other in a randomized manner to see if the treatment effect is real. And, in fact, that would be very difficult to do in something like this, because the infection rates are very low, so you need a huge sample size.

This study simply looked at trends over time and infection rates. And the reduction in infection rates shown in the study could be due to the adoption of conductive fabric warming or it could be due to other outside factors.

Q. What other outside factors could have influenced it?

A. Well, it could be anything. Improvement in surgical practices, perhaps. There's an antibiotic switch that was occurring somewhere in the study's period. You could have a different group of physicians operating. These are all uncontrolled things that don't get caught with observational

ALBRECHT

research.

Q. There's statistical methodology to at least account for known variables for different periods of time, aren't there?

A. Yeah.

Q. For -- for example, you could do a multivariate analysis, right?

A. And one was performed.

Q. In the paper itself, on table, is that, on page 15 -- no, table -- table Roman Numeral II, page 1542 --

A. Okay.

Q. -- that was a univariate analysis, right?

A. Yes.

Q. And nowhere in the -- the text of the -- the paper do you indicate that the analysis that is performed there is univariate, right?

A. I'm not sure that that distinction matters. So one at a time versus many at a time variable, it doesn't change the design of the study being observational versus randomized, because that's what you need to make a definitive conclusion.

Q. You could have done a multivariate analysis,



ALBRECHT

couldn't you?

A. Not exactly.

Q. Because you didn't have enough information of the variables?

A. Well, to prove what? What would the result be? How would it be different if we did a multivariate analysis?

Q. Are you saying it wouldn't make any difference?

A. It would present a similar picture, I believe.

Q. Did you try a multivariate analysis to --

A. Well, what factor did you need adjustment for? Because that's what multivariate analysis does.

Q. So did you -- let's -- first of all, you did the statistical analysis that's presented in this paper, correct?

A. I did, yes.

Q. Okay. What efforts did you undertake to see if there were other variables that could have influenced the infection rate that you could then account for through a multivariate analysis?

1 ALBRECHT

2 A. I asked the coauthors who had the infection  
3 data, so McGovern, Reed, from the estates  
4 over there, what factors would be important  
5 to look at in doing an analysis, and we  
6 pretty much followed the standard path you  
7 would in a clinical paper for looking at  
8 things. You start with a univariate analysis  
9 and kind of say, Are effects there. And I'm  
10 looking through the research here -- just  
11 hold on. Let me reacquaint myself with how  
12 we did this. (Reviews documents.)

13 No, we did -- this is a multivariate  
14 analysis, if you look at this. Because if  
15 you look at the patient-warming device in  
16 table 2 --

17 Q. Yeah.

18 A. -- I think we give the odds ratios for the  
19 outcome both for knee and hip in the text of  
20 the body, which would be in one group versus  
21 the other, I believe. Let me look through  
22 real carefully. I'm going to have to -- in  
23 fact, if you give me a minute to just read  
24 this, I can respond a little more clearly to  
25 what your questions will be.

1 ALBRECHT

2 Q. Absolutely.

3 MR. C. GORDON: What we'll do is  
4 we'll take a break and print out clean  
5 copies.

6 THE VIDEOGRAPHER: We're going off  
7 the record at 12:34 p.m.

8 (Whereupon, a brief recess  
9 was taken.)

10 THE VIDEOGRAPHER: This is video  
11 number 3 in the deposition of Mark Albrecht.  
12 Today is October 7th, 2016. We're going back  
13 on the record at 1:02 p.m.

14 BY MR. C. GORDON:

15 Q. Before we went off the record we were  
16 starting to talk about the Exhibit 8, which  
17 was one of your papers and the one that had  
18 the observational study component to it --

19 A. Yup.

20 Q. -- right?

21 And I want to focus on the  
22 observational component right now --

23 A. Okay.

24 Q. -- and talk about the other stuff later.

25 You -- you obtained the data from

ALBRECHT

Dr. Reed, right?

A. The hospital he's at, yes.

Q. Okay. When -- when did you first meet  
Dr. Reed?

A. I can tell by the papers here what a date  
would be, but I'm guessing around 2010 would  
the first time we met up, something like  
that, 2009. I wish I could tell you exactly.  
That stuff is kind of fuzzy for people. I'm  
not a big date rememberer --

Q. And -- and --

A. You probably figured that out by now.

Q. I'm not looking for precision, just how  
did -- how you meet him?

A. Well, there's a network of folks that do  
research in patient warming and people have  
interest in it, so just kind of pinging  
around here and there and people know each  
other and he got introduced to us. Maybe it  
was through Scott Augustine, I believe.  
That's probably who made the introduction.  
But I could be wrong, it could have been some  
other path too. It's kind of one community.

Q. Where -- where did you first meet him, in

1 ALBRECHT

2 England, the U.S.?

3 A. Probably the U.S. I think -- boy, I'm trying  
4 to get the order of events, did I go out  
5 there first to meet with him or did he come  
6 here. I would guess he probably came here  
7 first.

8 Q. The -- the study that's in Exhibit 8, that's  
9 got the two components to it --

10 A. It does.

11 Q. -- from the outset was it planned that there  
12 would be two components or did it start out  
13 as one and the other one was added?

14 A. That's a great question. As we were kind of  
15 embracing the problem and thinking it through  
16 wondering what would we need in terms of data  
17 that's available and what would we like to  
18 assess, this was brought up as something that  
19 was of interest, the observational component.

20 We definite -- definitely planned to  
21 look at the airflow characteristics in a  
22 laminar theater in some of the  
23 higher-performing ones like the UK has, so  
24 that was thought of. And I think -- I -- I  
25 think Mike Reed brought the infection data to

1 ALBRECHT

2 the table that he had, some of that  
3 available, and he would like to look at that  
4 too just to see how it kind of all painted  
5 together in a picture.

6 Q. Did you go over to England for the actual --  
7 the airflow study part of it?

8 A. Yes.

9 Q. At -- at that point when you were in England  
10 for that part, was it already contemplated  
11 that you would be doing the observational  
12 study on the infection data?

13 A. In all truthfulness, I don't know when that  
14 came in.

15 Q. Okay.

16 A. That's a big e-mail log, huh?

17 Q. It is.

18 (Whereupon, Exhibit 10 was  
19 marked for identification.)

20 BY MR. C. GORDON:

21 Q. Exhibit, what is that, 10?

22 MR. B. GORDON: Ten.

23 THE WITNESS: What is this? Oh,  
24 this is the data, okay.

25 MR. B. GORDON: So you can read

1 ALBRECHT

2 this.

3 THE WITNESS: Well, now that I  
4 know what I'm looking at.

5 MR. B. GORDON: No, I meant old  
6 guys like me and Corey. I need glasses to  
7 read this.

8 MR. C. GORDON: (Indicating.)

9 MR. B. GORDON: Oh you have  
10 bifocals okay.

11 MR. C. GORDON: I also have a  
12 magnifying glass.

13 THE WITNESS: I don't think that  
14 will help either.

15 BY MR. C. GORDON:

16 Q. I have something that's going to help. But  
17 first I want to establish that -- that is a  
18 printout of the data that Dr. Reed would have  
19 provided to you and from which you generated  
20 your statistical analysis that became the  
21 observational component of Exhibit 8?

22 A. I'm assuming, but there's no way for me to  
23 verify something like this.

24 Q. I want to walk you through a little bit of it  
25 and see if it rings -- rings a bell.

1 ALBRECHT

2 There -- there appear to be three  
3 different hospital -- hospitals involved  
4 there, three different two digit -- two  
5 initial codes there, do you see that?

6 A. Okay. Op code or -- let's see.

7 Q. I don't have it in front of me but --

8 MR. B. GORDON: Is there a legend?

9 THE WITNESS: It's a big table.

10 Wow. Okay. There probably is a number or --  
11 well, I wonder if there is with this one or  
12 not. Okay.

13 BY MR. C. GORDON:

14 Q. The -- I don't have -- oh, I do have a copy.

15 Under, "B, Site"?

16 A. Oh, yeah. Okay, cool.

17 Q. You have, "HX, MT," and, "WG"?

18 A. That sounds right.

19 Q. WG is for Wansbeck General, right?

20 A. I believe so.

21 Q. And the data that you based Exhibit 8 on were  
22 data only from Wansbeck General, right?

23 A. Boy, I've got to look now. I think so. Just  
24 hold on. These are very detailed questions,  
25 you have to think back. (Reviews documents.)



1 ALBRECHT

2 At our hospital, yeah, I believe so.

3 Q. Okay. And with that I think I'll see if I  
4 can make things a little easier.

5 (Whereupon, Exhibit 11 was  
6 marked for identification.)

7 BY MR. C. GORDON:

8 Q. I'll give you Exhibit 11.

9 MR. C. GORDON: Careful, the  
10 staple is sharp.

11 MR. B. GORDON: Okay.

12 BY MR. C. GORDON:

13 Q. And I will represent to you that Exhibit 11  
14 is a document that we created from the  
15 original source file that was Exhibit 10.

16 A. All right.

17 Q. And what we did was limit the site field to  
18 just WG, Wansbeck General.

19 A. Okay.

20 MR. B. GORDON: When you say,  
21 "We," you mean --

22 MR. C. GORDON: My paralegal.

23 MR. B. GORDON: Okay.

24 MR. C. GORDON: Okay?

25 BY MR. C. GORDON:

1 ALBRECHT

2 Q. So -- and you -- you have the full --  
3 Exhibit 10 is the full document, so you don't  
4 have to take my word for it, you can, you  
5 know, we can go back and forth to compare.

6 A. I would have no means to do so with something  
7 like this, but, yeah.

8 Q. It would take a long time. But on the things  
9 that -- that are going to matter, you --  
10 you -- you know, can cross reference it,  
11 because they -- every one of them has a -- a  
12 unique identifying number --

13 A. All right.

14 Q. -- on the first column.

15 We also limited the columns in order  
16 to get the --

17 A. Sure.

18 Q. -- information on one page that I -- that  
19 wanted to talk to you about. Again, all the  
20 information is available for you. Somewhere  
21 we do have a sheet that I think is the field  
22 codes, and I can find that if that matters.

23 But what I believe Exhibit 11  
24 reflects, called out from Exhibit 10, are all  
25 the hip and knee procedures performed at

1 ALBRECHT

2 Wansbeck from October 2nd, 2007, to  
3 December 23rd, 2010. And I believe, if you  
4 look at Exhibit 10, that is also the date  
5 range of the Wansbeck General --

6 A. Okay.

7 Q. -- data.

8 In the far right field under, "Deep  
9 Infection" --

10 A. Uh-huh.

11 Q. -- you'll see periodically --

12 A. Yup.

13 Q. -- a deep infection or a bacterial strain and  
14 then it -- a date. And that date -- just so  
15 you see what we're doing, let's -- let's take  
16 a look at the first one that shows up. It --  
17 it -- it has the unique identifier 145.

18 A. Yup.

19 Q. And if you look at --

20 MR. B. GORDON: Where -- where are  
21 you, Corey? Okay.

22 MR. C. GORDON: I'm sorry, you  
23 know what, I don't think the numbers did  
24 stay. I thought they did.

25 MR. B. GORDON: You're talking

1 ALBRECHT

2 about this enterococcus, whatever?

3 MR. C. GORDON: Yeah.

4 THE WITNESS: It's a type of  
5 bacteria. Okay. So 145 is WG 72. What is  
6 the hell is 72? Yeah, it looks like it's  
7 crossing.

8 BY MR. C. GORDON:

9 Q. So I think if you look at Exhibit 10,  
10 starting at page Bates numbers  
11 AUGUSTINE\_ 00005198 because this is a  
12 humongous Excel spreadsheet it goes across --

13 A. I do see it here, 30th of October, 2007.

14 Q. And you have to go five pages in on the  
15 Exhibit 10 to see the data we extracted,  
16 which is the -- the bacterial strain and the  
17 date of diagnosis.

18 A. Yup.

19 Q. The date of the procedure, I think, is under,  
20 "Op Date." And, again, I apologize if I -- I  
21 may not be able to locate it very quickly,  
22 but I know I've seen somewhere what looked  
23 like the descriptions of the fields.

24 A. Okay.

25 Q. But focusing on the procedure, the operation

1 ALBRECHT

2 date, the date of the infection, I think I'll  
3 be -- you know, I'm going to ask -- I'll be  
4 able to ask --

5 A. Okay.

6 Q. -- the questions I want to ask. And if  
7 there's anything in there that you want to  
8 know more about, you can look --

9 A. Okay.

10 Q. -- at the full set of data or you want me to  
11 go find the -- what I believe are the field  
12 identifiers, I'm happy to do that, but --

13 A. Okay.

14 Q. -- I think we might be able to get through  
15 that.

16 The study that the -- Exhibit 8, the  
17 study that you actually published in the  
18 observational component of it, you started  
19 the -- well, strike that.

20 For the observational study, you  
21 looked -- you divided the retrospective data  
22 you had into three components, right?

23 A. Yup.

24 Q. One was Bair Hugger only, one was a  
25 transition or crossover period --

ALBRECHT

A. Yup.

Q. -- and one was a period when only HotDog was used, right?

A. Yup.

Q. And as I understand it, you disregarded, for purposes of any of your statistical analysis, that crossover period?

A. That's what as a group we decided to do, yup.

Q. Okay. So you were just comparing the -- the first period when Bair Hugger was the warming modality used and the period when HotDog was --

A. Conductive fabric, yes.

Q. Conductive fabric. It was HotDog, wasn't it?

A. Yes.

Q. And you started the Bair Hugger only period as of July 1st, 2008, correct?

A. Boy, I would have to -- it looks like it here on the graph, yes.

Q. The -- the -- the -- from here on out or for the next few minutes for sure we will probably want precision, so please consult --

A. Okay.

ALBRECHT

Q. -- whatever you need to consult to --

A. Looking here, yes, July.

Q. The data you had available to you started in October of 2007, right?

A. I don't know, because I don't have the exact data in front of me that was used. I've been given this table telling me that this is it.

Q. The Exhibit 10, I will represent to you was produced by Augustine -- I don't know if it was Dr. Augustine personally, but I think it was Augustine Medical, pursuant to a subpoena.

A. Uh-huh. Did that come from the test report folders, was that the actual analysis file?

Q. Electronically I have no idea.

A. Because that's very important to know, because that would govern why the decisions for the time periods are what they are.

Q. Tell me the two different files you said.

A. So there was a file that was used for analysis that was agreed upon by the group. So there's -- there's actual statistical code that runs this and there's data that underlies that. And for me to be certain on

1 ALBRECHT

2 anything that's going on, I would need access  
3 to that.

4 MR. B. GORDON: Well, and I -- for  
5 that reason I'm going to interpose an  
6 objection to the reliability of this chart,  
7 Exhibit 11, prepared by your paralegal and  
8 you, as being an adequate and fair  
9 representation of the statistical data that  
10 would be comprised in Exhibit 10. I just  
11 want a standing objection to the use of this,  
12 because I don't know that it's the same  
13 thing.

14 THE WITNESS: That's -- I see the  
15 date in this and I'm not sure what that's  
16 about.

17 MR. C. GORDON: I think we're  
18 talking about two different things.

19 Ben, to the extent you -- you know,  
20 I mean, we prepared Exhibit 11, and if there  
21 are any discrepancies between it and --

22 MR. B. GORDON: Right, because he  
23 can't authenticate anything in --

24 MR. C. GORDON: He can't  
25 authenticate Exhibit 11, clearly.



1 ALBRECHT

2 BY MR. C. GORDON:

3 Q. Do you recall looking at data in the form of  
4 an Excel spreadsheet?

5 A. Yeah, at some point something came over as an  
6 Excel spreadsheet that we started from.

7 Q. And as you sit here today, you don't have any  
8 recollection of whether there was or was not  
9 data provided to you prior to July 1st, 2008?

10 A. I don't know. I have no recollection on that  
11 detail.

12 Q. Okay. So would it be -- let's see if this  
13 jogs your memory. If you -- if you -- if you  
14 look at either Exhibit 10 or 11, although 11  
15 is a lot easier --

16 MR. B. GORDON: Just give me a  
17 standing objection to 11 and then you can use  
18 it, if he can make sense of it, that's fine.

19 BY MR. C. GORDON:

20 Q. Yeah, and -- and -- what I'm going to -- all  
21 I'm doing this is to -- to -- to jog your  
22 memory, you know, I'm not -- I'm not asking  
23 you to authenticate about what I'm about to  
24 say. But if you were to count the number  
25 of -- of infections that arose within 60 days

1 ALBRECHT

2 of the operating procedure, which was the  
3 criteria used, right?

4 A. I believe so. I'd have to look through here  
5 and what was sent to me for the data and the  
6 definitions. Hold tight. Again, without the  
7 exact code in front of me, it's very hard for  
8 me to faithfully answer some of these  
9 questions, because if they're very detail  
10 oriented, I sometimes won't be able to tell  
11 you because I just simply don't know the  
12 detail. Let's see here. (Reviews document.)  
13 Okay. "In order to standardize a duration of  
14 follow-up, only infections presenting within  
15 60 days of surgery were included," okay.

16 Yup.

17 Q. And, again, I'm not asking you to -- to  
18 verify this or refute it or anything, but if  
19 you were to count from Exhibit 10 --

20 A. Okay.

21 Q. -- which it's a lot easier to do on  
22 Exhibit 11, the number of procedures  
23 performed at Wansbeck between October 1st,  
24 2007, and June 30th, 2008, the total number  
25 of -- of hip and knee prostheses -- or joint

1 ALBRECHT

2 replacements, arthroplasties, is 534. And if  
3 you count the number of infections that  
4 appear on Exhibit 10 for Wansbeck General  
5 Hospital during that period of time that  
6 occurred within -- within -- within 30  
7 days -- or 60 days within the operation date,  
8 there are a total of 5.

9 A. Well, and this is the data pool that's used  
10 here then the broader file, I would imagine.

11 Q. Exhibit 10?

12 A. I would think so. See, it says, "Our data,"  
13 it doesn't say -- let me look here.  
14 (Reviews document.) I want to be very  
15 precise if you're asking this question. I  
16 see where you're going.

17 Q. And -- well, on this issue, let me just tell  
18 you that -- that -- you don't have to believe  
19 me, you can do it yourself, but I spent a lot  
20 of time trying to correlate the data as  
21 reflected in the paper with the data in the  
22 data file.

23 A. All right.

24 Q. And if it's not just Wansbeck General,  
25 there's no -- it isn't even close. But if it

1 ALBRECHT

2 is Wansbeck General only, then it's really  
3 close, although not exact.

4 A. Okay.

5 Q. And I'm not going to show you now, but I  
6 think there's -- you had a subsequent e-mail  
7 exchange with Dr. Reed where you talked about  
8 how the data was not exactly a hundred  
9 percent accurate.

10 MR. B. GORDON: Objection to  
11 counsel's testimony.

12 MR. C. GORDON: And -- and I'll  
13 sustain the objection, I'm not --

14 THE WITNESS: Can you show me the  
15 e-mail, please?

16 MR. C. GORDON: Yeah, we -- we can  
17 pull that out.

18 MR. B. GORDON: There's not a  
19 question, so...

20 BY MR. C. GORDON:

21 Q. My whole point in raising this is do you  
22 remember any discussion about let's start in  
23 the middle of 2008, because that if we start  
24 it as early as October 2007, the infection  
25 rate is pretty low?

ALBRECHT

A. I don't recall. But if you have an e-mail, it obviously happened.

Q. No, I'm not saying I have an e-mail that says that. I'm just --

A. No, I don't recall that.

Q. Okay. So you have no recollection of any discussion about moving the -- the -- you know, or -- or adjusting the start --

A. Not to my knowledge, no.

Q. Okay. All right. So the study period --

A. Keep in mind, all these were very carefully talked about amongst us as a group, you know, the author, as what we chose for the analysis.

Q. Okay. And the group you're talking with was who?

A. Closely working with McGovern and Reed on how to think about this stuff, and Carluke, Partington, yes.

Q. And Scott Augustine too?

A. Yes, he was involved in discussions.

Q. He was copied on all the e-mails too, right?

A. He may have been on some of them.

Q. Okay. The Bair Hugger only period --

1 ALBRECHT

2 A. Okay.

3 Q. -- and we need to be precise, was 7/1/08 to  
4 2/28/10, correct?

5 A. 7/1/08 to 2/28/10. Okay, yeah, that might be  
6 about right.

7 Q. The crossover period was 3/1/10 to 5/31/10;  
8 is that right?

9 A. That looks about correct.

10 Q. Well, I don't want to be about correct on  
11 this one --

12 A. Are there dates in the paper?

13 Q. Yeah.

14 A. Okay. If those are the dates that are in the  
15 paper, then that's what it was.

16 Q. I think that appears on page 1540.

17 A. Okay. Okay. July 1st. So, yeah, if these  
18 are the numbers or the dates here, we can be  
19 as accurate as we can be.

20 Q. And then the HotDog only period was 6/1/10 to  
21 12/30 -- excuse me, 12/31/10, correct?

22 A. 6/1/10 to 12/31/10, let's see here.

23 (Reviews document.) Yes, 1st of June, 2010.

24 Q. Let's work backwards in time. In the paper  
25 you report that in the HotDog only period

1 ALBRECHT

2 there were three infections that -- that met  
3 the criteria, correct?

4 MR. B. GORDON: Could you reread  
5 that? I'm sorry, I missed it. I can read it  
6 right here, that's okay.

7 THE WITNESS: It's based on the  
8 table, yes, I have three infections.

9 MR. C. GORDON: Okay.

10 BY MR. C. GORDON:

11 Q. Now, if you would look at Exhibit 11.

12 A. Okay.

13 Q. And, again, feel free to cross-reference to  
14 Exhibit 10.

15 MR. B. GORDON: Standing  
16 objection.

17 BY MR. C. GORDON:

18 Q. If you count the infections for that time  
19 period --

20 A. Okay.

21 Q. -- June 1st, 2010, to 12/31/2010, there are  
22 actually four, correct?

23 A. I would have to physically count these, but  
24 that's not what our data says here. The data  
25 set that was analyzed there was three.

1 ALBRECHT

2 Q. Go ahead and count.

3 A. I see one in this article --

4 Q. Be sure you look at the --

5 MR. B. GORDON: June --

6 BY MR. C. GORDON:

7 Q. I think there's -- I -- I start at the very  
8 end of the study period, so look --

9 A. Okay. I've got one here on 10/30/07.

10 Q. No --

11 A. I'm sorry.

12 Q. -- I'm sorry, we'll get to those. If you  
13 jump ahead to -- I guess they're not  
14 page-numbered, but way in where it's -- where  
15 sort of towards the very bottom of the page  
16 it starts with 6/1/2010 there.

17 A. Okay.

18 MR. B. GORDON: Unfortunately, the  
19 pages aren't numbered.

20 THE WITNESS: Okay. So 6/1. So  
21 we got one, two, three. Yeah, I count four,  
22 and the fourth one occurring on 11/22/10.

23 MR. B. GORDON: Just, again, I  
24 want to object to the extent that we can't  
25 know definitively that this is an accurate



1 ALBRECHT

2 reflection of what's actually in the data  
3 set, because it's not from the data set or  
4 it's an extraction from counsel from the data  
5 set.

6 BY MR. C. GORDON:

7 Q. Yeah, and for the four infections, if you --  
8 you know, go ahead and look at --

9 A. Well, that's what I was going to say, because  
10 there may have been a reason --

11 Q. Yeah, and that's exactly why -- if there's a  
12 reason, I'd like to know. That's --

13 A. And I -- honestly, in those calls I probably  
14 sent the e-mail to Mike or Paul about someone  
15 on this and there was a determination, but  
16 it's so long ago you can't tell.

17 (Reviews document.)

18 Yeah, I don't know. I can't tell if  
19 anything on here gives me any insight into  
20 this.

21 Q. Let's see if this jogs your memory about --

22 A. Please.

23 Q. -- issues.

24 (Whereupon, Exhibit 12 was  
25 marked for identification.)

1 ALBRECHT

2 BY MR. C. GORDON:

3 Q. I'm showing you Exhibit 12. And this is  
4 some -- a document you produced, a series of  
5 e-mails between you and Dr. Reed from 2012,  
6 right?

7 A. Yeah.

8 Q. Or two -- so I guess 2011, 2012.

9 A. So we start at the back, forward here.

10 Q. It looks like it. In fact, let's start at  
11 the -- at the back page, which --

12 A. Yeah, please.

13 Q. -- the first e-mail where -- and the subject  
14 says, "Hi, Mike. Say, the data file you sent  
15 me doesn't match the earlier one for  
16 overlapping cases"; do you see that?

17 MR. B. GORDON: Which page are you  
18 on?

19 MR. ASSAAD: Which page are you  
20 looking at?

21 MR. C. GORDON: The Bates number  
22 3576.

23 MR. ASSAAD: Which e-mail? The  
24 last page?

25 MR. C. GORDON: It's the last

1 ALBRECHT

2 e-mail, but it starts at the bottom of the  
3 second page or second to last page.

4 MR. B. GORDON: The subject says,  
5 "Hi, Mike."

6 THE WITNESS: "Mike, I've done a  
7 quick analysis of the new data trends"; is  
8 that what you're looking at?

9 MR. C. GORDON: Yes.

10 BY MR. C. GORDON:

11 Q. And you say, "The data files are not totally  
12 consistent in regards to the data that the  
13 BR, JB, JS article was based upon."  
14 That -- that's a reference to Exhibit 8,  
15 right?

16 A. Okay. So this e-mail is after the analysis  
17 of this, yes.

18 Q. Okay. And the second to the last paragraph  
19 of your first e-mail that starts this chain  
20 is you -- you tell Dr. Reed, "So I'm giving  
21 you a graphic for the Wansbeck data, but do  
22 not distribute it for it," quote, "Slightly,"  
23 close quote, "Conflicts with study data due  
24 to different reporting practices in your  
25 data. The relevant info supported in your

ALBRECHT

figure is," and then you go on to give odds ratios, confidence intervals.

Does this reflect -- refresh your recollection that you had seen data that you thought slightly conflicted with the study data?

A. Well, we did an analysis on the file that went into here, right, and then we got a new file that he wanted updated statistics on after the article was published and everything was done. And it looks like it didn't line up a hundred percent, so I ran the analysis, I'm not sure what's going on, and that's kind of where this thread comes from.

Q. And I want to make it very clear, I have no idea if Exhibit 10 is the original data --

A. I don't either.

Q. -- or the -- the newer data that's slightly conflicted.

A. It's probably the slightly conflicted, because this one would match up, whatever it is.

Q. Okay. Going back to what you report for the

ALBRECHT

number of infections of Bair Hugger only  
study period --

A. Okay.

Q. -- in -- on Exhibit 8, and I think that's on  
page 1542, you report 31 -- 32, correct?

A. Excuse me. Okay. So patient-warming device,  
infections, developing infection for forced  
air, 32.

Q. Okay. And you're more than welcome to take  
the time to do that, but my -- I -- I count  
in that Bair Hugger only period on the data  
on Exhibit 10 that there were actually 31  
infections in -- at Wansbeck.

A. All right.

Q. As you -- again, as you sit here today --

A. I don't know.

Q. I guess -- well, number one, you can go back  
and look at Exhibit 12. You did a  
recalculation of the odds ratio --

A. With the updated data, yes.

Q. Yeah, and --

A. That would be different than the data here.

Q. Right. What was the odds -- what was the  
odds ratio as you reported in the paper?

1 ALBRECHT

2 A. Okay. So the paper odds ratio was 3.8 with a  
3 confidence interval of 1.2 to 12.5.

4 Q. Okay.

5 A. And the updated one here had an odds ratio of  
6 2.98, and a confidence interval that's still  
7 significant.

8 Q. So the odds ratio going down --

9 A. It did.

10 Q. -- would be -- would be consistent with too  
11 high a number on the Bair Hugger side and too  
12 low a number on the HotDog only side, right?

13 A. There's not too high a number, too low a  
14 number. The data file that was assessed that  
15 was screened by the clinicians, these are the  
16 numbers that represent it.

17 Q. I -- right. I didn't mean to say a mistake  
18 was made. I'm saying that the -- the  
19 difference between 3.8 and 2.9 --

20 MR. B. GORDON: Eight.

21 BY MR. C. GORDON:

22 Q. -- 8, could be accounted for by having  
23 lesser infections in the forced -- in the  
24 Bair Hugger only period and more infections  
25 in the HotDog period, correct?

1 ALBRECHT

2 A. It could be due to a reduction in Bair Hugger  
3 infections, HotDog stays the same. It could  
4 be due to an increase in HotDog infections,  
5 Bair Hugger stays the same. You know,  
6 there's many ways to get an odds way to move.

7 Q. And but the odds -- if -- if in fact there  
8 were -- the data you analyzed the second time  
9 around had fewer infections in the HotDog  
10 period and more infections in the  
11 Bair Hugger -- sorry. Strike that.

12 A. The infections could have been the same, the  
13 number of controls could have changed, so we  
14 have fewer -- more non-infections and that's  
15 going to push it down, because you're looking  
16 at odds ratios.

17 Q. But one way that the odds ratio might have  
18 changed is if the total number of infections  
19 attributed to the Bair Hugger only period  
20 went -- was lower and the total number of  
21 infections attributed to the HotDog only  
22 period was higher?

23 MR. B. GORDON: Objection to form,  
24 calls for speculation, not supported by the  
25 facts in evidence.

1 ALBRECHT

2 THE WITNESS: If you add  
3 infections to the one group and not to the  
4 other, you will move the odds ratio.

5 MR. C. GORDON: Okay.

6 THE WITNESS: There's about four  
7 different mechanisms to push it in different  
8 directions.

9 MR. C. GORDON: Right.

10 BY MR. C. GORDON:

11 Q. And I -- I don't want to spend a lot of time,  
12 you know, on 31 versus 32 or 3 versus 4, I  
13 just --

14 A. Sure.

15 Q. -- does that --

16 A. Yeah, they paid me to -- this is after my  
17 time. I was out at a new job. They wanted  
18 the file updated, so I did that for them  
19 using the same methods with the new data  
20 file, and this is what was returned.

21 Q. Okay. Are you aware of any letters to the  
22 editor or any efforts undertaken to correct  
23 the odds ratio that was reported?

24 MR. B. GORDON: Object to form.

25 THE WITNESS: This isn't a



1 ALBRECHT

2 correction needed, because the new data was  
3 added, so the cohort is different in this  
4 versus what's in the paper. So the new data  
5 and the trend does persist. So Mike is  
6 asking, "I'm keen to see what's happened  
7 since we looked at this last, so there's an  
8 old file attached in case you don't have it  
9 and the new data." So he augmented the data  
10 set and that's why there's the different  
11 number.

12 MR. C. GORDON: Okay.

13 BY MR. C. GORDON:

14 Q. So what -- what was it that's slightly  
15 conflicted with the study data?

16 A. I have no clue. I've got to look at this  
17 very carefully. (Reviews document.)

18 So it looks like in the new file  
19 they sent me there was that 60 days concern.  
20 He didn't have a date, so he couldn't clip it  
21 in the same manner, and I think that was part  
22 of it.

23 So he sent me a file that wasn't as  
24 complete as the one we initially used and it  
25 was missing one of the fields we did to

ALBRECHT

figure out the number of infections, and so this was just an internal update for him.

This wasn't reanalysis of the original study. This was just, Hey, Mark, I've got a data file here, I wanted to see for my own knowledge if this trend is persisting given a little more data, could you help me out.

Q. Did you write up a paper that had a revised analysis or an updated analysis of the additional data?

A. Yeah, and it was in my -- let's see here. You guys should have got that somewhere. In my Gmail dump I would have expected it, but this might not have come from Gmail, this might have been from my U of M account, which is toast.

Q. What do you mean it's toast?

A. It doesn't exist anymore, so in doing the document pull I couldn't get anything from there.

Q. Okay. Well --

A. Do you have that updated study document? I would be happy to walk you through it and try

1 ALBRECHT

2 and understand why they're different.

3 Q. Again, I don't want to focus too much on the  
4 difference between 31 and 32 and 3 and 4,  
5 because I don't think that is a good use of  
6 time at this point.

7 A. Okay.

8 MR. B. GORDON: Then we'll object  
9 to your use of it for any other reason.

10 BY MR. C. GORDON:

11 Q. What I do want to focus on, though, is let's  
12 start with Figure 7 --

13 A. Okay.

14 Q. -- in this study on page 1543.

15 MR. ASSAAD: Exhibit 8?

16 MR. C. GORDON: Correct.

17 BY MR. C. GORDON:

18 Q. And there's a -- this figure is a -- is a  
19 depiction of infection rates in the  
20 Bair Hugger period, the transition period and  
21 the conductive -- or the HotDog period,  
22 right?

23 A. Yup.

24 Q. Now, for the Bair Hugger only period, the  
25 infection rate is drawn as a uniformed

1 ALBRECHT

2 straight line, correct?

3 A. It's an average of the period.

4 Q. It's an average that -- that was my question.

5 And if you look at the plots on  
6 the -- at the very top, I assume those  
7 plots -- the -- the little circles are the  
8 individual infections corresponding to the  
9 time period in which they occurred?

10 A. Yup, those are the raw data points plotted  
11 and they're moved up and down a little bit,  
12 it's called jittering, so they try not to lay  
13 on top of one another so you don't over plot.

14 Q. Could you, if you had wanted to, plotted  
15 these infection rates, rather than as an  
16 average over this entire time period, as  
17 broken it down into smaller time periods?

18 A. So like a -- a smoothed curve?

19 Q. Yes.

20 A. You could, but it wouldn't correspond with  
21 the model results in the contingency table.  
22 We like to match the contingency table  
23 whenever possible to the raw data figure so  
24 the results kind of all tie up.

25 So if you look here, the infection

ALBRECHT

rate that's presented here is the estimate is the same infection rate that's used to get your odds ratio in table number 2, and that's why we kind of chose to present the data with that type of a picture. It's just so the model matches up and you can plot the model and its air bounds.

Q. Okay. Looking at the -- those plots, would you agree that the -- the spacing of those -- of the infections is not uniform throughout that Bair Hugger period?

A. Absolutely.

Q. They seem to be clustered a little bit at the beginning and a little bit more at the end, right?

A. They could be due to a random process. It's sometimes hard to tell. The eye always picks out a pattern where none is sometimes present.

Q. Okay. I think you mentioned this before, but there was a change in -- in antibiotics?

A. Oh, yeah.

Q. When did that change occur?

A. Let's see here, so it's actually in the

1 ALBRECHT

2 paragraph right below it to the left. And,  
3 again, this is -- Mike Reed would give a lot  
4 more context to this, if you want, or  
5 Paul McGovern but --

6 Q. We'll all stipulate to that.

7 A. Yup.

8 MR. C. GORDON: Certify that,  
9 please, as a submission to the high court in  
10 London.

11 THE WITNESS: Okay. So although  
12 no infection control changes were made after  
13 2010. So in the methods part that you talk  
14 about the prophylaxis change, there's a very  
15 clear -- I believe. Let me read through  
16 this. (Reviews document.) Okay, so that's  
17 that piece. Where is the data stuff? Joint  
18 infection data, here we go. (Reviews  
19 document.) Okay. From July 2008 to February  
20 2009 they had one regimen. In March 2009  
21 onward they changed.

22 BY MR. C. GORDON:

23 Q. You're talking about the antibiotic?

24 A. Well, that, and it looks like they had a  
25 blood clotting drug change too.

1 ALBRECHT

2 Q. For the moment, let's -- let's focus on the  
3 antibiotic change.

4 A. Okay.

5 Q. The -- during the Bair Hugger only period,  
6 the only antibiotic used for the -- the  
7 period of July 1st, 2008 to February --

8 THE WITNESS: Do you have a pencil  
9 I could borrow? Is that okay?

10 MR. B. GORDON: Yeah.

11 THE WITNESS: Sorry, I want to  
12 draw a line on this graph just so --

13 MR. C. GORDON: Yeah.

14 THE WITNESS: So go ahead and tell  
15 me again what you're saying.

16 BY MR. C. GORDON:

17 Q. From February -- excuse me, July 1st, 2008,  
18 to 2/28/09, the only prophylactic antibiotic  
19 used was Gentamicin, correct?

20 A. 2/28.

21 MR. B. GORDON: Object to I just  
22 want to make sure that's accurately stating  
23 the facts.

24 THE WITNESS: Let's see what we  
25 got here. (Reviews document.) Okay. Okay.

1 ALBRECHT

2 We've got a line. All right.

3 MR. C. GORDON: Okay.

4 BY MR. C. GORDON:

5 Q. And then from March 1st, 2009, to the end of  
6 the -- the study period, the prophylactic  
7 antibiotic regimen was a combination of  
8 Gentamicin and Teicoplanin, right?

9 A. In February 2010 they went back to  
10 Tinzaparin --

11 Q. No, that's the -- the --

12 A. The blood clotter?

13 Q. The blood clotter, yeah.

14 A. Okay. So let's just say that that's the  
15 case.

16 Q. Well --

17 A. Again, this is the details that the surgeons  
18 are more familiar with.

19 Q. Well, the question I want to ask you is  
20 whether you had any discussion with Mike Reed  
21 or anyone else about why they switched from  
22 having just one antibiotic to a combination  
23 of two antibiotics?

24 A. The reasons for that switch, I'm unsure.  
25 Surgical practice changes all the time, so I



1 ALBRECHT

2 think they're probably just following  
3 protocol changes, but that would be a guess  
4 on my part. I don't know why they would  
5 change.

6 Q. Did you ask?

7 A. I didn't -- I didn't ask why they changed,  
8 no, at least to my knowledge, I'm not sure.

9 Q. So did you have any discussion with Mike Reed  
10 as to whether he thought the use of  
11 Gentamicin alone was potentially a problem?

12 MR. B. GORDON: Object to form,  
13 calls for speculation, asks for a medical  
14 opinion he's not qualified to answer.

15 THE WITNESS: We talked about it  
16 as it pertained to the analysis of the data,  
17 and that's why there's a big caveat here in  
18 the discussion that outlines the study does  
19 not establish a causal basis for this  
20 association and calls out the antibiotic  
21 change.

22 BY MR. C. GORDON:

23 Q. That was actually something that a -- that a  
24 peer reviewer from the journal asked you to  
25 include, right?

1 ALBRECHT

2 A. I'd have to see the e-mails. I don't recall.

3 Q. Did -- in any of your communications with  
4 Dr. Reed, did he ever tell you that he had  
5 come to the conclusion that there is no  
6 evidence for the use of systemic Gentamicin  
7 as prophylaxis in primary elective total hip  
8 arthroplasty and total knee arthroplasty  
9 surgery?

10 A. Not to my knowledge, unless there is an  
11 e-mail on that. It's a long time ago. I  
12 don't remember.

13 Q. Well, if -- if today you were to be told that  
14 Dr. Reed had concluded that Gentamicin --  
15 there's no evidence for using Gentamicin  
16 alone was an antibiotic for prophylaxis in  
17 arthroplasties, would that impact how you  
18 view the validity of the comparison of the  
19 Bair Hugger only to the HotDog only period  
20 given that there was a period of time when in  
21 the Bair Hugger portion when only Gentamicin  
22 was used?

23 MR. B. GORDON: Objection to form,  
24 compound, assumes facts not in evidence,  
25 improper foundation, calls for medical

1 ALBRECHT

2 opinion.

3 THE WITNESS: As a factor in the  
4 model, there's a transition period here that  
5 happened. This is an observational study.  
6 These things aren't controlled for. You  
7 can't make a causal inference, and we did  
8 not. The study does not establish a causal  
9 basis and that's -- there's a lot of  
10 compounding factors that could be at play.

11 BY MR. C. GORDON:

12 Q. And you, in this paragraph on page 1545, the  
13 first full paragraph on that page, you  
14 mentioned that there are --

15 A. 1545?

16 MR. B. GORDON: 45?

17 THE WITNESS: Forty-three?

18 MR. C. GORDON: 1543, yeah. Ben's  
19 point about my eyes.

20 THE WITNESS: Which one now?

21 BY MR. C. GORDON:

22 Q. The -- the line, "The study does not  
23 establish the causal basis for the  
24 association," and you go on to say that, "The  
25 data are observational and may be compounded

1 ALBRECHT

2 by other infection control measures  
3 instituted by the hospital"; do you see that?

4 A. Yes.

5 Q. The next sentence starts, "For example," and  
6 then you talk about the change in antibiotic  
7 and thromboprophylaxis protocols, right?

8 MR. B. GORDON: Is there a  
9 question?

10 THE WITNESS: This wouldn't be me  
11 talking, this would be the clinical  
12 researchers writing their sections of the  
13 article.

14 BY MR. C. GORDON:

15 Q. Do you know why two examples were given as  
16 opposed to an attempt to comprehensively list  
17 other infection control measures instituted  
18 by the hospital that may have confounded the  
19 results?

20 MR. B. GORDON: Objection to form,  
21 calls for speculation.

22 THE WITNESS: I wouldn't know.  
23 I'm not an employee of the hospital. You'd  
24 have to ask someone who is to know what they  
25 were. I listed the ones that were important

1 ALBRECHT

2 in their minds.

3 BY MR. C. GORDON:

4 Q. So that was your determination to only  
5 mention antibiotic and thrombo --

6 A. No, it was not my determination. This  
7 article is a joint collaboration between six  
8 authors. They all had the same conclusion in  
9 reading through the manuscript, drafting it  
10 and approving what went out.

11 Q. Well --

12 A. So, no, it's not mine.

13 Q. Would you agree that one possible conclusion  
14 that this paper suggests is that the change  
15 in infection rates that you report was a  
16 result of changing from the Bair Hugger to  
17 the HotDog?

18 MR. B. GORDON: Objection to form.

19 THE WITNESS: We report a  
20 difference, a significant difference in the  
21 odds ratio for those time periods knowing  
22 that there are other things that could have  
23 been associated with that change, such as  
24 those you've highlighted here, the change in  
25 antibiotic and the change in blood clotting

1 ALBRECHT

2 drugs.

3 BY MR. C. GORDON:

4 Q. Did you -- and as a -- as the statistician  
5 doing the -- the -- the statistical analysis  
6 here, could you have done a multivariate  
7 analysis that would have accounted for the  
8 changes in infection control measures  
9 instituted by the hospital?

10 MR. B. GORDON: Objection to form,  
11 asked and answered.

12 THE WITNESS: Not easily. We had  
13 talked about that. And I think the reasoning  
14 was that the data was pretty sparse. And I  
15 need to look carefully at that. We did  
16 discuss it. (Reviews document.)

17 In fact, I think that follow-on  
18 e-mail, we have one here where we have enough  
19 data that we can kind of take out some of the  
20 data for the period of the difference in --  
21 well -- we did our best to control for it  
22 with the data at hand. I'm trying to  
23 remember the exact reasoning we chose. Let  
24 me think about that question for just a  
25 second.

1 ALBRECHT

2 If we had more data, yes, the answer  
3 would be it's simple to do that.

4 BY MR. C. GORDON:

5 Q. And by more data, that would include more  
6 data on what the infection control measures  
7 were and when they were instituted, right?

8 A. Well, if you want a simple thing on just the  
9 antibiotics --

10 Q. Okay.

11 A. -- we can think about that. Again, this is a  
12 while ago some of these decisions were made,  
13 so it takes a while for me to get back to the  
14 place we were at.

15 Q. Understood.

16 A. So I don't really want to ramble here, so let  
17 me just think for a second about your  
18 question. (Reviews documents.)

19 Given that I'm not as close to the  
20 data as I once was and the decision-making  
21 process around why the analysis is or was  
22 what it is, you know, this is five years plus  
23 ago, my recollection is there was something  
24 to do with the number of observations in the  
25 grouping making that very difficult to do,

1 ALBRECHT

2 but I can't recall exactly what our choices  
3 were.

4 Q. Let's go back to the -- to the changes that  
5 you did talk about in the -- in the study.  
6 In addition to the antibiotic change, there  
7 was a change in the -- what -- what the paper  
8 describes as thrombo -- thromboprophylaxis.

9 A. Yeah. That's blood clotting, right?

10 Q. An anti-blood clotting --

11 A. Yeah.

12 Q. And the change was from Tinzaparin to -- it's  
13 Rivaroxaban in the United States. Or  
14 Rivaroxaban -- I'm sorry. The change was  
15 from Tinzaparin to Rivaroxaban, which is also  
16 known as Xarelto, back to Tinzaparin. And do  
17 you recall --

18 A. I'm looking at this.

19 Q. Read it if you want, I just --

20 A. Give me the dates on that so I can draw them  
21 on my graph.

22 Q. Well, I want it to be your testimony, but it  
23 appears to me that the Rivaroxaban period was  
24 August 1st, 2009, to February 28th, 2010.

25 MR. B. GORDON: And you can point



1 ALBRECHT

2 him to the page 1540 to be fair.

3 MR. C. GORDON: I could --

4 THE WITNESS: Yeah, I'm just  
5 trying --

6 MR. C. GORDON: -- but you did.

7 MR. B. GORDON: Okay. Thank you.

8 THE WITNESS: Okay. So we've got  
9 another period in there. Okay.

10 MR. C. GORDON: Okay.

11 BY MR. C. GORDON:

12 Q. Do you recall having any discussions about  
13 the fact that they had switched from one  
14 anti-clotting drug to another, and after  
15 seven months they went back to the original  
16 anti-clotting drug they were using?

17 A. I was informed of this and we talked about  
18 it, but the reason why they did that I don't  
19 know. Things change all the time in the  
20 hospital.

21 Q. You never had any discussion with Mike Reed  
22 or Paul McGovern about why they -- they went  
23 back to the original one after seven months?

24 A. Not that I recall on what the reasoning was.

25 Q. And so you didn't have any discussion as to

1 ALBRECHT

2 whether that could have impacted infection  
3 rates, right?

4 MR. B. GORDON: Objection; calls  
5 for speculation, asked and answered and calls  
6 for a medical opinion.

7 THE WITNESS: I'm not the  
8 clinician in this case, and it's their  
9 judgment to figure out, you know, what the  
10 treatment regimens are and how those relate  
11 to the risks a patient -- a patient faces and  
12 what choices they make.

13 So in doing the analysis we talked  
14 about the fact that there was a change, but  
15 what that change means clinically, I have no  
16 way to interpret.

17 MR. C. GORDON: Okay.

18 BY MR. B. GORDON:

19 Q. If you wanted to eliminate the antibiotic and  
20 the anti-blood clotting changes as potential  
21 factors, would the -- would the best way be  
22 to look at a period in the Bair Hugger only  
23 period when the same antibiotic and  
24 anti-clotting prophylaxis -- prophylaxis regimen  
25 was used that was used in the HotDog period?

1 ALBRECHT

2 A. If there is such data, yes.

3 Q. As you -- as you sit here today, are you  
4 aware that there -- that there was such data?

5 A. Well, so let me look at this here. I recall  
6 us redoing something after the fact as a  
7 follow up to even this article here that we  
8 had further updated data, and I don't know if  
9 you have had in your hands, but I think we  
10 should talk about that if you have it,  
11 because that would highlight this question a  
12 little more.

13 Q. I just want to -- for the moment I want to  
14 stick to the data that are in --

15 A. Okay.

16 Q. -- that actually reported in the paper.

17 A. Yeah. It's an observational study. We're  
18 looking for things at this point and we're  
19 doing univariate tests, because the data  
20 isn't that deep, there's factors changing  
21 under foot, it's not properly controlled  
22 where you're adjusting for these factors in a  
23 statistically valid sense, and so it's  
24 just -- single tests were done, things were  
25 highlighted, the patient-warming device did

1 ALBRECHT

2 stick out, the caveats were listed, and you  
3 can see the -- the rate of infection over the  
4 periods, and there are some issues that, yes,  
5 there was a confounder of antibiotic change,  
6 yes, there was a confounder of clotting agent  
7 change.

8 Q. Okay. Let's talk about those two  
9 confounders. During the Bair Hugger only  
10 period, there -- the antibiotic protocol was  
11 a combination of Gentamicin and Teicoplanin,  
12 right?

13 A. Okay.

14 MR. B. GORDON: Objection; asked  
15 and answered.

16 BY MR. C. GORDON:

17 Q. And during the Bair -- the HotDog only  
18 period, the anti-clotting agent that was used  
19 was Tinzaparin, correct?

20 MR. B. GORDON: Asked and  
21 answered.

22 THE WITNESS: Okay.

23 BY MR. C. GORDON:

24 Q. And if -- well, during the period of  
25 March 1st, 2009, to July 31st, 2009, it was

1 ALBRECHT

2 a -- it was a Bair Hugger only -- it was  
3 Bair Hugger only at that point still,  
4 correct?

5 MR. B. GORDON: Asked and  
6 answered.

7 THE WITNESS: Yes, it looks that  
8 way.

9 BY MR. C. GORDON:

10 Q. And the antibiotic prophylaxis was the same  
11 Gentamicin and Teicoplanin that was used in  
12 the HotDog only period, correct?

13 MR. B. GORDON: Asked and  
14 answered.

15 THE WITNESS: I'm going to have to  
16 map this out here. Do you have a sheet of  
17 paper I could borrow?

18 MR. C. GORDON: Oh, absolutely.  
19 I'll give you a whole pad. (Hands paper.)

20 And I understand I --

21 THE WITNESS: There's a lot of --

22 MR. C. GORDON: I killed many  
23 trees doing this.

24 THE WITNESS: Yeah. Well, if you  
25 want an answer that makes any kind of sense.

1 ALBRECHT

2 Okay. I don't catch the switchback  
3 you're talking about. I see the Gentamicin,  
4 the Gentamicin plus Tinzaparin for the  
5 antibiotic, and then that holds, unless I  
6 missed something in the reading.

7 BY MR. C. GORDON:

8 Q. Which -- I'm sorry, which switchback?

9 A. So reading this out, all right,  
10 unfortunately, the prophylactic antibiotic  
11 regimen was not constant during the study  
12 period from July 2008, which is the start,  
13 right, to February 2009. A single dose of  
14 Gentamicin was given at induction.

15 Q. Right.

16 A. Okay. So we have Gentamicin up to February  
17 of 2009. Okay. In March of 2009, so right  
18 then, this was changed to Teicoplanin, I  
19 don't even know how you pronounce that, and  
20 Gentamicin --

21 Q. And that stayed the same for the rest of the  
22 period?

23 A. Yes, yes.

24 Q. So from March 1st on there's no difference in  
25 the antibiotic prophylaxis, right?

1 ALBRECHT

2 A. Yes. From March 1st, yes.

3 Q. So let's overlay now the change in the --

4 MR. B. GORDON: Blood thinner.

5 BY MR. C. GORDON:

6 Q. -- the anti-blood clotting.

7 A. Okay.

8 Q. According to your paper, it says from August  
9 2009 to February 2010 Rivaroxaban was  
10 provided, but in February 2010 to the end of  
11 the study this reverted to Tinzaparin.

12 A. August 2009 to February 2010, they flip it  
13 and they go back, right? Okay. So August  
14 2009 to 2010, let's see how that lines up.

15 Yeah, so we always have something  
16 changing under foot, because antibiotics  
17 aren't the same before March 2009 or whatever  
18 and after, and then we do have a clotting  
19 agent that is the same at the beginning and  
20 at the very end, but in the middle there's a  
21 difference.

22 So we do have one thing that did  
23 change under foot, though, that, you know, it  
24 doesn't revert back, right?

25 Q. Well, no, I -- I'm trying to understand this,

1 ALBRECHT

2 but I -- it looks to me like there are five  
3 months in the Bair Hugger only period when  
4 the patients were getting the same  
5 antibiotics and the same anti-clotting agent  
6 the patients got in the HotDog only period.  
7 From March 1st, 2009, to July 31st, 2009,  
8 patients got Gentamicin and Teicoplanin and  
9 Tinzaparin, right?

10 A. March 1st, 2009, to -- say again?

11 Q. July 31st, 2009.

12 A. That's a pretty short time period, March 1st,  
13 2009, to July 31st, 2009.

14 Q. Yeah, how many months is that?

15 A. What would that be, five, six-ish. That's  
16 not a lot of data.

17 Q. Yeah. How many months was the HotDog only  
18 period?

19 A. Let's see, what did that run here? Hold on.  
20 (Reviews document.) So it was June 1st,  
21 2010, to January 1st, 2011; is that right?  
22 Yes?

23 Q. It's your study.

24 A. That's what it looks like. No, I'm looking  
25 at it quick.



1 ALBRECHT

2 Q. There's a 2.5 year period starting  
3 July 30th -- or July 1st, 2008, so I'm  
4 assuming that that's -- the 2.5 year period  
5 would have ended on December 31st, 2010.

6 MR. B. GORDON: Objection to  
7 counsel's testimony. It's not a question.

8 BY MR. C. GORDON:

9 Q. But it's your study, so tell me.

10 A. Yeah, it looks like June to the first of the  
11 year, yup.

12 Q. So how many months is that?

13 A. Seven-ish, right. Well, and again, this is  
14 an observational study and we present all  
15 these factors that are at play.

16 Q. Okay.

17 A. And there are confounders, you've clearly  
18 identified them.

19 Q. Well, but my -- my point is or my question is  
20 would you agree that if you just looked at  
21 the period of March 1st, 2009, to July 31st,  
22 2009, in the Bair Hugger only period and  
23 compared that to the HotDog only period,  
24 you'd be eliminating the confounders of  
25 antibiotics and anti-blood clotting right?

1 ALBRECHT

2 MR. B. GORDON: Object to form.

3 THE WITNESS: Maybe assuming other  
4 things didn't change under foot too that  
5 aren't accounted for.

6 BY MR. C. GORDON:

7 Q. I'm just talking about those two confounders,  
8 which are the -- the -- well, strike that.

9 Those are the only two confounders  
10 you actually mentioned in your paper, right?

11 A. Well, there's more.

12 MR. B. GORDON: Objection to form.

13 THE WITNESS: There is something  
14 here that talks about -- well, other factors  
15 such as details of blood transfusion,  
16 obesity, incontinence, you know, those kind  
17 of predictors were also left out.

18 BY MR. C. GORDON:

19 Q. But those aren't changes in infection control  
20 practices, right, those are patient-specific  
21 host immunity factors?

22 A. Yeah. So there is a period where there is  
23 similar antibiotic use in both groups and  
24 similar blood-clotting agent use.

25 Q. Not similar, it's identical?

ALBRECHT

A. Identical.

Q. Okay. So if you compared those two periods, then antibiotics and anti-blood clotting wouldn't be potential confounders, right?

A. Assuming other things didn't change. Again, this isn't a design trial.

Q. Right. Just those two things, though.

A. Because in a period of that time to that time, other factors are going to change under foot. Yes, if you wanted to have those two factors be the same, that's what you'd do.

Q. Okay. So can you tell from the lines you drew on the chart how many infections there were in the Bair Hugger period when the antibiotics and the anti-blood clotting were the same as in the HotDog period?

A. I don't have a clue. You may have run that number.

Q. Well, I'm just -- can you tell from the chart? Didn't you draw lines?

A. So March 1st, 2009 -- as best I can. So March 1st, 2009, to July 31st -- wait a sec. March -- there's only a handful.

Q. Does that graph have enough detail that

1 ALBRECHT

2 you -- that you could count?

3 A. It looks like two or three.

4 Q. Okay.

5 A. Maybe four. I'm unsure. I'd have to get  
6 that date just right.

7 Q. Okay. And here's where Exhibit 10 and  
8 Exhibit 11 can come into play.

9 A. Okay.

10 Q. If you -- as I say, if you want to look at  
11 Exhibit 10, that's fine. I believe the data  
12 are going to be the same as Exhibit 11.

13 A. I don't know what this is, yeah.

14 Q. If you look at Exhibit 11, it's a little  
15 easier to count them up.

16 MR. B. GORDON: Same objection  
17 raised before about Exhibit 11 not being  
18 authentic.

19 THE WITNESS: I'm assuming you've  
20 done the count. How many did you see?

21 MR. C. GORDON: I see three.

22 THE WITNESS: Three, okay. I see  
23 three or four there, so...

24 Okay. We're looking for March 1st  
25 through July 31st. I count three from this

1 ALBRECHT

2 file, yes.

3 MR. C. GORDON: Okay.

4 BY MR. C. GORDON:

5 Q. And that's based on your -- the graph that  
6 you plotted, that's in the range of what --  
7 what --

8 A. Three to four, yes.

9 Q. There's not a lot of detail in that graph, so  
10 you can't, with precision, know the dates,  
11 but one thing you can't tell from the graph  
12 regardless of the precision of the -- of when  
13 exactly the individual dots are falling on  
14 the timeline, is you can't tell how many  
15 procedures were being performed, right?

16 A. On the bottom, no, that's hard to do.

17 Q. And in order to come up with an infection  
18 rate, you've got to have both the enumerator  
19 and the denominator, right?

20 A. Correct.

21 Q. So in order to know how many -- what the  
22 infection rate was in that window of time  
23 when during the Bair Hugger period the  
24 patients were getting the same antibiotics  
25 and the same anti-blood clotting as in the

ALBRECHT

HotDog only period, you'd have to know --  
you'd have to count up the number of  
procedures that were done in that same  
period?

A. Yes, you would.

Q. Please do.

A. From here, (indicating)?

Q. Yes.

A. You literally want me to do this? Have you  
done this?

Q. I have.

A. Okay. What's the number you come up with?

Q. Three seventeen.

A. Okay. So 3 in 317 --

Q. I'm sorry, 317, that's HotDog. Two  
ninety-three?

A. Okay. So 3 and 293. So this is 3 versus  
368. Okay.

Q. Where do you get 368?

A. I'm looking at the paper. I just wanted to  
see what the conductive fabric had for number  
of operations.

Q. And -- and, I'm sorry, where -- can you just  
point me to --

1 ALBRECHT

2 A. Table 2.

3 Q. Table 2?

4 A. Yup.

5 Q. That says 371, doesn't it?

6 A. Well, I have 3 and 368, so for conductive  
7 fabric.

8 Q. It's the 368 I'm not getting.

9 MR. B. GORDON: Three plus --

10 THE WITNESS: Oh, I'm just --  
11 sorry, I'm giving you the number of successes  
12 and failures. Yes, that would be 371 in  
13 total.

14 BY MR. C. GORDON:

15 Q. By the way, if you -- if you count the number  
16 of Wansbeck procedures for HotDog only in  
17 Exhibit 10 --

18 A. Okay.

19 Q. -- there's only 317. Any idea why the 371  
20 reported in the paper, but 317 --

21 MR. B. GORDON: Objection --

22 THE WITNESS: I don't have the raw  
23 data.

24 MR. B. GORDON: Just for the  
25 record, we don't know if it's the same data,

1 ALBRECHT

2 we established that earlier.

3 MR. C. GORDON: Okay.

4 BY MR. C. GORDON:

5 Q. So what's -- what's -- what's the infection  
6 rate for 3 out of 293?

7 A. Well, you have a calculator. It's virtually  
8 comparable in this cut of time.

9 Q. I'm sorry?

10 A. It's virtually comparable to the other group  
11 in this cut of time. So we're at 1.02  
12 percent.

13 Q. Okay.

14 A. And for 371 you want? That's where I assume  
15 you're going.

16 Q. Do -- do -- sure, do -- well, you already did  
17 that. That's already in the paper.

18 A. Yeah. So that's .8 percent. All right.

19 Q. And if you were to do -- count 4 infections  
20 in that Bair Hugger period, and we'll say it  
21 was 371, what would the infection rate be?

22 MR. B. GORDON: Objection to the  
23 mischaracterization of the data and he's  
24 already testified he doesn't know if it's the  
25 same data.



1 ALBRECHT

2 THE WITNESS: So if you want me to  
3 tell you what 4 divided by what?

4 MR. C. GORDON: Well, use 371.

5 THE WITNESS: Okay. You're at  
6 10 percent. I'm sorry, you're at 1 percent.

7 MR. C. GORDON: It may be 371.

8 BY MR. C. GORDON:

9 Q. So if you had compared the five-month period  
10 when Bair Hugger was used with the same  
11 antibiotic and same anti-thromboembolism  
12 drugs as was used in the seven months of the  
13 HotDog period, you're the statistician --

14 A. Those would not be significant for that cut  
15 of time, significantly different.

16 Q. Not even close to significantly different,  
17 right?

18 A. They would not be significantly different. I  
19 don't need to run an analysis to figure that  
20 part out.

21 Q. Why didn't you do that, what we just did?

22 A. It's an observational study. We plotted the  
23 data, we put the concerns in, we talked as a  
24 group what to do and we looked at the  
25 timeline.

1 ALBRECHT

2 Q. When you say you plotted the data, there's no  
3 way somebody reading that paper could know  
4 what the infection rate was during the  
5 Bair Hugger only period when the same -- you  
6 have the same prophylaxis -- antibiotic and  
7 anti-blood clotting regimen was used, right?

8 MR. B. GORDON: Objection to form,  
9 assumes facts not in evidence, misstates the  
10 record.

11 THE WITNESS: As a group, this is  
12 where the data analysis landed. We did a  
13 bunch of univariate tests on the basic  
14 things, we did a transition period on the  
15 devices, and we reported it as observational  
16 data. This is not a clinical trial with a  
17 definitive answer.

18 BY MR. C. GORDON:

19 Q. Well, and in response to a reviewer's  
20 comments, you noted that there were changes  
21 to the antibiotics and thromboprophylaxis  
22 during the periods, right?

23 A. Yes.

24 Q. But you could have completely eliminated  
25 those as confounders by doing what we just

1 ALBRECHT

2 did, right?

3 A. If you throw away the other parts of the  
4 data. Again, it's an observational graph and  
5 we're just looking at trends.

6 Q. Well, and you would agree that the trends for  
7 the Bair Hugger period and the HotDog period  
8 using the same antibiotics and same  
9 anti-blood clotting drugs --

10 A. I don't know what else is going on.

11 Q. -- are the same?

12 MR. B. GORDON: Objection --

13 THE WITNESS: I don't know what  
14 else is going on under the surface though.

15 MR. B. GORDON: -- argumentative,  
16 asked and answered.

17 THE WITNESS: I mean, we see -- we  
18 see a reduction in infection over time here,  
19 a time based trend to this component too  
20 that's going on, and who knows what did it.  
21 We provide a couple hypotheses about it, we  
22 state that this is not a causal basis --  
23 casual -- or causal basis. We identify  
24 looking for some of these stat tests what was  
25 here. The antibiotic, unfortunately, was not

1 ALBRECHT

2 tested in the way that you described.

3 BY MR. C. GORDON:

4 Q. What do you mean it wasn't tested?

5 A. That analysis or that cut of the data was not  
6 presented in the table. And now that you  
7 bring that up, it would have been nice to  
8 have that in there.

9 Q. If you had presented that, it wouldn't have  
10 been very interesting, would it?

11 MR. B. GORDON: Object to the  
12 form, argumentative.

13 THE WITNESS: Not true. This was  
14 about an airflow disruption paper that also  
15 had some joint data accompanying it. The  
16 major focus of this paper was about the  
17 surgical field and how the airflow is  
18 affected by ways.

19 BY MR. C. GORDON:

20 Q. You know that Scott Augustine has been  
21 marketing the HotDog with the claim that this  
22 paper demonstrates that switching from  
23 Bair Hugger to HotDog results in a 76 percent  
24 reduction in surgical site --

25 MR. B. GORDON: Objection to form,

1 ALBRECHT

2 misstates the facts --

3 BY MR. C. GORDON:

4 Q. -- don't you?

5 MR. B. GORDON: -- misstates the  
6 evidence. It doesn't say 76 percent, you  
7 need to check your facts.

8 MR. C. GORDON: Seventy-four  
9 percent. I'm sorry. Thank you.

10 THE WITNESS: I'm not sure what  
11 he's been doing for marketing nowadays. I  
12 have not been in touch with that company in  
13 some time except for updating the analysis.

14 BY MR. C. GORDON:

15 Q. Would you agree that if -- if he were to  
16 claim that your paper, Exhibit 8, stands for  
17 the proposition that switching from  
18 Bair Hugger to HotDog can result in a  
19 74 percent reduction in surgical site  
20 infections, that that would be wrong?

21 MR. B. GORDON: Objection to form,  
22 calls for speculation, argumentative.

23 THE WITNESS: It depends on your  
24 interpretation of the data. I see a time  
25 trend here, I see a period when two devices

1 ALBRECHT

2 are in use, I see other confounding factors  
3 that might be at play. I don't know. It's  
4 uncertain, like a lot of these things are.

5 BY MR. C. GORDON:

6 Q. Well, one thing that is certain, though, is  
7 that if you factor out the antibiotics and  
8 the anti-thromboembolism drugs as potential  
9 confounders, there's no difference?

10 A. If you cut your data --

11 MR. B. GORDON: Objection; asked  
12 and answered. Sorry.

13 THE WITNESS: If you cut your data  
14 to the period we just discussed and run the  
15 analysis on the cut of time there to there  
16 and compare those two groups in the way we  
17 just did, yes, there is not a significant  
18 difference.

19 MR. C. GORDON: Okay.

20 BY MR. C. GORDON:

21 Q. And let's spend a little bit more time on  
22 the -- the change in the thromboprophylaxis.

23 A. Okay.

24 Q. That period was August 1st, 2009, to  
25 February 28th, 2010, right?

1 ALBRECHT

2 A. So August 1st, 2009, okay.

3 Q. To 2/28/2010. I'm -- I'm -- can you tell  
4 from your little scatter plot there how many  
5 infections occurred during that period of  
6 time?

7 A. Which period, say again?

8 Q. August 1st, 2009, to 2/28/2010.

9 A. 2/28 to 2010. Sorry, this isn't ordered like  
10 that, I've got to look at the months. So  
11 that would be March 1st, 2010?

12 Q. Yeah.

13 A. Okay. So August 1st, 2009. August 1st,  
14 2009, okay, to March 1st, 2010. Sorry.  
15 Okay, I've got a rough cut on that. Is that  
16 the start of the transition?

17 Q. That's correct, yes.

18 A. Okay.

19 Q. Can you -- can you count the number of dots  
20 in that Rivaroxaban time period?

21 A. Seventeen-ish, if I got that right.

22 Q. If you count the -- on Exhibit 11, or go  
23 through Exhibit 10, I come up with 18, but  
24 whether it's --

25 A. Okay, 17 or 18, very similar.

1 ALBRECHT

2 Q. Of course, again, the reader of your paper  
3 wouldn't have the denominators, so there we'd  
4 have to go to Exhibit 10, or the data that's  
5 extracted from it on Exhibit 11.

6 A. Uh-huh.

7 Q. And, again, feel free to count it, but I'll  
8 represent to you that every time I counted  
9 it, and it was several, it was 401 procedures  
10 done in that time period.

11 A. Okay.

12 Q. So what's the rate of infection using --  
13 yeah.

14 A. 4.2 to 3 percent. Call it 4.3 percent.  
15 Okay.

16 Q. And, you know, again, I understand this --  
17 this is a complex statistical thing that  
18 you -- you would need to do, but if you were  
19 to compare the period, that Tinzaparin period  
20 when the antibiotics were the same to the  
21 Rivaroxaban time period we were just saying  
22 where you would have a -- in other words,  
23 1.02 percent to what did you say 4 point --

24 A. Three. 4.3 we'll call it.

25 Q. Okay. Would that, just eyeballing it, and



1 ALBRECHT

2 I -- again, I understand you need to do a  
3 sophisticated analysis to really say but --

4 A. Not in this case. So you said 4.3 percent  
5 for this period versus which period are we  
6 talking about?

7 Q. The -- the 1.02 when it was Tinzaparin, but  
8 it was still the same antibiotics.

9 A. Well, no, if it's 1 -- 1 percent versus  
10 4 percent, I can tell you that those are  
11 different, yeah.

12 Q. Maybe that explains why they went back to  
13 Tinzaparin?

14 A. Could be.

15 MR. B. GORDON: Objection to form.

16 BY MR. C. GORDON:

17 Q. You never had a discussion about that?

18 A. We talked that the antibiotics changed and we  
19 would do some tests here, show the different  
20 devices. We did want to do the forced-air  
21 warming versus conductive-fabric warming  
22 because we saw an airflow difference, so we  
23 wanted to present that, and this  
24 observational data was presented as such.

25 Q. You keep -- you kept talking about -- I don't

1 ALBRECHT

2 recall your exact words, but that this was a  
3 trendline or --

4 A. It's a mean.

5 Q. Yeah. But -- and if you compare the  
6 Tinzaparin, same antibiotics, to the  
7 Rivaroxaban, same antibiotics period, it  
8 wouldn't be a straight line, would it?

9 A. No.

10 Q. One would be way down and one would be way  
11 up, right?

12 A. Uh-huh. Yup.

13 Q. And, in fact, when they switched back from  
14 the Rivaroxaban, which is also the time they  
15 started switching over to Bair Hugger,  
16 infection rates went way back down, right?

17 A. There is an up/down swing here that  
18 corresponds with multiple things happening,  
19 yeah.

20 Q. Just factoring in the change in Rivaroxaban,  
21 would you agree that -- strike that.

22 You said there are multiple things  
23 going on. What else are you aware of?

24 MR. B. GORDON: Objection; asked  
25 and answered three or four times.

1 ALBRECHT

2 THE WITNESS: So let's draw the  
3 timeline on a sheet of paper so we can talk  
4 about it a little more concretely, because  
5 I'm jumping around in my head here with this  
6 stuff as we're going to different pieces --

7 MR. C. GORDON: Fair enough.

8 THE WITNESS: -- and it doesn't  
9 help make this very clear.

10 Okay. So we've got antibiotic,  
11 blood and device, right, are the three  
12 factors we're talking about here in our  
13 discussion.

14 MR. C. GORDON: Uh-huh. Yes.

15 THE WITNESS: Okay. I'm just  
16 going to make some hashes on the thing here.  
17 Christ, I need a Gantt chart to do this.  
18 It's ridiculous.

19 MR. C. GORDON: I'm sorry?

20 THE WITNESS: I need a Gantt chart  
21 to do this on a computer almost it's like --  
22 all right.

23 BY MR. C. GORDON:

24 Q. I guess you guys don't use graph paper  
25 anymore, huh?

1 ALBRECHT

2 A. No, it's been a while.

3 Q. You probably don't even use a slide rule?

4 A. I don't do engineering anymore, I do data  
5 science nowadays.

6 Q. You didn't use a slider rule.

7 A. No.

8 MR. C. GORDON: Ben, you didn't  
9 even use a slider rule.

10 MR. B. GORDON: No. I remember  
11 them, but I didn't use them.

12 MR. C. GORDON: I used a slider  
13 rule.

14 MR. GOSS: I have my grandfather's  
15 slide rule at home. I'm not implying  
16 anything, Corey.

17 MR. C. GORDON: Well, son, my  
18 yellow picket slide rule is packed away in a  
19 box somewhere that my kids will have to get  
20 rid of it when I die.

21 THE WITNESS: So that goes on from  
22 that point forward, that's what I was missing  
23 in my head.

24 THE VIDEOGRAPHER: Corey, we've  
25 got about 15 minutes left on this tape.

1 ALBRECHT

2 Would now be a good time to change it out.

3 MR. C. GORDON: Yeah, why don't  
4 want you change it out.

5 THE VIDEOGRAPHER: We're going off  
6 the record at 2:40 p.m.

7 (Whereupon, a brief recess  
8 was taken.)

9 THE VIDEOGRAPHER: This is video  
10 number 4 in the deposition of Mark Albrecht.  
11 Today is October 7th, 2016. We're going back  
12 on the record at 2:49 p.m.

13 BY MR. C. GORDON:

14 Q. I don't remember if there was a question  
15 pending, but you had wanted to --

16 A. I did, and I understand exactly what you're  
17 bringing up now. There was a period of  
18 capable antibiotic regimen in both groups and  
19 similar prophylaxis for blood clotting, yup,  
20 and one could compare those two periods and  
21 come to the conclusion that that also could  
22 be the result of these differences in  
23 infection rates, the data does support that,  
24 that's a possibility too.

25 Q. When you say, "Possibility too," what --

1 ALBRECHT

2 A. Well, you don't know what it is. How are you  
3 to say that that's any more likely than it is  
4 the difference in device. It's not a  
5 randomized controlled trial, it's an  
6 observation study. We saw infection rates go  
7 kind of up and down and you're doing your  
8 best guess at it, and that's observation,  
9 it's imprecise it's not perfect. It's not a  
10 randomized controlled trial, which would give  
11 you a definitive answer. You just simply  
12 can't get one out of this type of data. And  
13 what someone else chooses to do with the data  
14 is up to them.

15 (Whereupon, Exhibit 13 was  
16 marked for identification.)

17 BY MR. C. GORDON:

18 Q. Let me show you Exhibit 13. What I  
19 particularly want to direct your attention to  
20 is the -- well, the graph that shows -- the  
21 graphic that shows the 3.1 percent, and then  
22 the arrow to 0.8 percent, and the line,  
23 "Forced-air warming discontinued, joint  
24 infections reduced 74 percent."

25 A. Okay.

1 ALBRECHT

2 Q. That -- and it's your study that's cited  
3 there, right?

4 A. Uh-huh.

5 Q. Do you -- you said people can do what they  
6 want with the data, but do you think that  
7 what you see here in Exhibit 13 is  
8 scientifically supported by your study?

9 A. In an observational sense, yes, it is, those  
10 are the numbers for the periods. This isn't  
11 the result of a randomized clinical trial. I  
12 don't know what constitutes sufficient data  
13 for marketing. A lot of people use data in  
14 different ways.

15 Q. Can you -- do you believe your study can in  
16 any way be used to support the conclusion  
17 that switching from Bair Hugger to HotDog  
18 will reduce surgical site infections?

19 MR. B. GORDON: Objection to form,  
20 asked and answered, calls for a medical  
21 conclusion.

22 THE WITNESS: There's  
23 observational data in here that shows a  
24 decrease in infection rates with the switch  
25 between devices, that is true, that is

1 ALBRECHT

2 confounded with antibiotics.

3 BY MR. C. GORDON:

4 Q. It's also confounded with prophylaxis --  
5 thromboprophylaxis?

6 A. Yes. It's observational in nature.

7 Q. And if you eliminate just those two  
8 confounders, there is no statistical --  
9 statistically meaningful difference --

10 MR. B. GORDON: Objection to form.

11 BY MR. C. GORDON:

12 Q. -- between Bair Hugger and HotDog, right?

13 A. This is not a randomized clinical trial. I  
14 don't know what effect led to what.

15 MR. B. GORDON: Object to form,  
16 misstates his testimony.

17 THE WITNESS: This is  
18 observational data.

19 BY MR. C. GORDON:

20 Q. Why do observational data? What's -- what's  
21 the purpose?

22 A. It's to identify trends that you may suspect  
23 in the data and bring it to question so  
24 someone can do a proper experiment further  
25 on, like a randomized trial.



1 ALBRECHT

2 Q. Your trendline was just an arithmetic mean  
3 across 23 months --

4 A. Uh-huh.

5 Q. -- right?

6 What -- having gone through the  
7 exercise that you've gone through now to  
8 compare one time period, just the Rivaroxaban  
9 versus the no Rivaroxaban, would you agree  
10 that a trendline that shows an arithmetic  
11 mean across the -- that entire time period is  
12 pretty misleading?

13 MR. B. GORDON: Objection to form.

14 THE WITNESS: I would have liked  
15 to have added that to the effects here so  
16 it's more clear what that did over the time  
17 period. Having you make me drill into it a  
18 little more clearly like that and not treat  
19 it as just a confounder that, well, it's  
20 there, so you can't truly trust this, you  
21 know, I would have dug in a little deeper and  
22 put an effect in the table, I think.

23 BY MR. C. GORDON:

24 Q. And if you had done that, tell me what --  
25 would that -- would you have been able to do

1 ALBRECHT

2 a multivariate analysis with that, is that  
3 the right term?

4 A. I still don't think we would have. I think  
5 we would have presented it that we looked for  
6 this effect, saw nothing, we looked for that  
7 effect, saw nothing, oh, antibiotics had an  
8 effect, forced air had an effect, now we need  
9 to figure this out with a trial.

10 So you'd do this in a univariate  
11 fashion still with observational data, in my  
12 opinion.

13 Q. If you were to analyze the data factor --  
14 taking into consideration antibiotics and  
15 the -- the Rivaroxaban, and -- and, in  
16 effect, factored those out, do you still  
17 think that there would -- even with  
18 observational data it would show a difference  
19 between Bair Hugger and HotDog?

20 MR. B. GORDON: Objection to form,  
21 misstates his earlier testimony.

22 THE WITNESS: I don't know. I  
23 would have to run a model. There's a period  
24 of time here which comes into play. This  
25 data, there's possibly not enough

1 ALBRECHT

2 infections -- infections to do a multivariate  
3 analysis like that where it's properly  
4 powered, just kind of looking at this. I'm  
5 not so sure we'd be able to tease out the  
6 effect of multiple factors at the same time  
7 with a data set that has, you know, few  
8 infections like that over multiple cuts of  
9 variables. So that can be difficult. You'd  
10 have to try.

11 BY MR. C. GORDON:

12 Q. Well, you'd agree with me that what we just  
13 teased out with just those two -- two  
14 variables, the antibiotics and the  
15 anti-thrombophylaxis -- thromboprophylaxis,  
16 resulted in two periods that were pretty  
17 comparable in both in duration and in number  
18 of procedures, right?

19 A. Yeah. I'd like to add that to a table as a  
20 univariate effect and do further  
21 experimentation to see what led to what.

22 Q. One of my associates grew up in California.

23 A. Sure.

24 Q. And in his -- his fond young -- young  
25 childhood memory is his family going to

1 ALBRECHT

2 Disneyland and his brother leaning over to  
3 him as they were driving to Disneyland and  
4 said, "Everybody who goes to Disneyland  
5 dies."

6 A. Okay.

7 Q. That's actually true, right?

8 A. All right. How is that relevant to this?

9 MR. B. GORDON: Object to the form  
10 of the question.

11 BY MR. C. GORDON:

12 Q. Well, you'd agree that it would be absurd to  
13 conclude from the fact that everybody who  
14 goes to Disneyland dies, that Disneyland has  
15 anything to do with people dying?

16 MR. B. GORDON: Object to form,  
17 calls for speculation, improper hypothetical.

18 THE WITNESS: I can't tell you  
19 from observational data if it's in change in  
20 device or if it's a change in antibiotics  
21 clearly, because other things are going on  
22 behind the scenes. This is a hypothesis.  
23 It's presented as such that there are these  
24 factors and if you compare the data in the  
25 way presented from here to here, you get that

1 ALBRECHT

2 effect.

3 I agree that an antibiotic effect  
4 would be nice to add to this graph and help  
5 explain the challenge a little more clearly  
6 that we're facing here.

7 BY MR. C. GORDON:

8 Q. Well, not just the antibiotic fact, but the  
9 anti-thromboprophylaxis fact, right?

10 MR. B. GORDON: That's just blood  
11 thinner.

12 THE WITNESS: Yeah. And a  
13 clinician would have to tell you what's  
14 relevant. I mean, you could put a lot of  
15 things in here too and say, Well, Larry was  
16 mopping the floors in this room for these  
17 days and that, and you can make this data so  
18 high dimensional you'll find all sorts of  
19 things that relate.

20 But I agree that the antibiotic  
21 piece is a real thing and some kind of an  
22 effect here, univariate effect presented in  
23 the same way as the other effects would be  
24 nice to have.

25 BY MR. C. GORDON:

1 ALBRECHT

2 Q. Were you ever made aware that at the  
3 beginning of the Bair Hugger period the  
4 laminar airflow system in one of the Wansbeck  
5 operating theaters was not functioning  
6 properly?

7 A. Not that I recall. I may have or may not, I  
8 don't know.

9 Q. Were you ever made aware of the fact that in  
10 2008 and 2009 the Northumbria Trusts were  
11 repeatedly advised by the National Health  
12 Service that their SSI rates for orthopedic  
13 procedures made them a high outlier compared  
14 to other trusts in the -- in the UK?

15 A. I had heard they were having infection  
16 problems, I was not sure of the details.

17 Q. Did anyone ever tell you that as a result of  
18 those infection problems, they instituted a  
19 wide range of infection controlled  
20 procedures?

21 MR. B. GORDON: Object to form,  
22 lack of foundation, calls for speculation.

23 THE WITNESS: No, I don't know the  
24 exact procedures they implemented.

25 BY MR. C. GORDON:

1 ALBRECHT

2 Q. Do you know any of them?

3 A. Well, we have a couple here, they are  
4 antibiotic changes. I'm not the clinical  
5 expert and I'm not close enough to this to  
6 know exactly what's going on behind the  
7 scenes at the hospital. You know, I  
8 really -- I'm unsure of what has happened.

9 Q. And -- and I know this is -- it is several  
10 years later, so I'm not expecting you to have  
11 a clear memory, but as a statistician doing  
12 this analysis, would it have been important  
13 to you to -- to know that in December of 2008  
14 the Wansbeck -- or the Northumbria Trust  
15 formed a committee specifically to develop  
16 ways to address the -- this outlier status of  
17 high infection rates?

18 MR. B. GORDON: Objection to form,  
19 calls for speculation, outside his expertise.  
20 He said he doesn't have the clinical  
21 background to answer.

22 THE WITNESS: This highlights the  
23 need for randomized studies of these things,  
24 so background factors like you're bringing up  
25 aren't confounded with the results we see.

1 ALBRECHT

2 BY MR. C. GORDON:

3 Q. Were you aware that during the Bair Hugger  
4 only period the -- they changed the surgical  
5 dressings that they used to a particular type  
6 of dressing that Mike Reed had believed,  
7 based on randomized clinical controls,  
8 reduced infection rates by about two-thirds?

9 A. I don't recall that detail.

10 Q. Would that have made any difference?

11 MR. B. GORDON: Objection to form.

12 THE WITNESS: I think details like  
13 that could have made it into the discussion  
14 about the other things that are confounding  
15 factors. Again, it's observational. None of  
16 these things are causative.

17 BY MR. C. GORDON:

18 Q. Is -- is there a point in time where all the  
19 observational data, or whatever observational  
20 data you're presenting, are confounded by so  
21 many cofounding factors that there's no point  
22 in drawing -- even presenting observational  
23 data?

24 MR. B. GORDON: Objection to form.

25 THE WITNESS: There's kind of an



1 ALBRECHT

2 art to that in publications. If you have  
3 some data and even if it might be wrong or it  
4 might not tell the truth -- not the truth,  
5 but tell the picture that's really  
6 underlying, right, sometimes you've presented  
7 in the hopes that you can get other people  
8 looking at it and that people can help  
9 explain the story.

10 BY MR. C. GORDON:

11 Q. And what -- what is -- what is the story that  
12 you told in this paper?

13 A. Well, it's not exactly a story, but it's a  
14 connection of a couple of research --  
15 research hypotheses, one of which is, you  
16 know, is there any kind of disruption to the  
17 airflow in the ventilation theater.

18 And then the other part is, well, if  
19 we're going to look at that and we have an  
20 effect of something that does that, you know,  
21 demonstrated here, is there a change in  
22 infection data that coincides with that. And  
23 so it had a focus like that, because we want  
24 to look and ask those direct questions that  
25 are linked.

1 ALBRECHT

2 Q. And the reasonable conclusion from people  
3 just reading that paper is that they are  
4 linked, right?

5 A. Well, it's a research article and it's an  
6 observational study, the data is. I  
7 believe -- let's see if we call it the need  
8 for a randomized clinical trial here. We may  
9 have well commented on that in the  
10 discussion. (Reviews documents.)

11 And there have been national studies  
12 that look at the effect of, you know, airflow  
13 and cleanliness in relationship of  
14 ventilation to improved outcomes, and that's  
15 kind of the piece that ties into this and why  
16 we're looking at this question, because we  
17 have something that we observe to disrupt  
18 airflow and we want to see if there was a  
19 change in infection period over that time  
20 given we had a device with some kind of  
21 mechanism that may or may not have done  
22 something to infection rates. It's a logical  
23 link to try and ask this question and see if  
24 there's a change.

25 Q. And now that we've gone through this

ALBRECHT

exercise, do you think if you had presented the data that would -- that showed that the infection rate when Bair Hugger was -- was used with the same antibiotics and the same anti-blood clotting regimen has -- in the HotDog period, there was no statistically significant difference between the infection rates, do you think that would have changed the -- the impact that this -- this paper would have had?

A. I wouldn't have done a multivariate analysis as you suggest there off the cut. I would have added the antibiotic effects to this table of univariate effects and left someone with the observational data to do some of their own thinking.

Typically, in an observational study, doing multivariate adjustments can be kind of tricky and you tend to stay away from them and use one test at a time just to kind of say, hey, is there a trend or not, does that trend look significant, I don't know what caused it.

So we'll just look at one trend a

1 ALBRECHT

2 time to kind of screen things that you're  
3 looking for, and that's all you're left with  
4 is a screening, well, is it associated or is  
5 it not, you don't know if it's the cause. So  
6 I don't know if it's the device, if it's  
7 antibiotics.

8 Q. If you had presented the analysis of  
9 antibiotics and -- and you keep saying  
10 antibiotics and I want to make sure that  
11 you --

12 A. And blood clotting.

13 Q. Okay. That's what I thought.

14 Whatever thought someone might have  
15 reading the paper as it exists now as to  
16 whether it's the device or something else,  
17 would you agree that if you had presented the  
18 information that we just went through about  
19 antibiotics and blood clotting, that the  
20 thoughts about the likely answers to that  
21 question might be different?

22 MR. B. GORDON: Objection; calls  
23 for speculation and invades into an area of  
24 medical expertise that he doesn't possess.

25 THE WITNESS: From a statistical

1 ALBRECHT

2 point of view, it would have identified two  
3 clear effects that probably need deeper  
4 investigation that do call into question, you  
5 know -- it highlights the fact that it's  
6 observational data.

7 BY MR. C. GORDON:

8 Q. And it would have made it a lot harder for  
9 anyone to --

10 A. They still could have done that if they  
11 wanted to, because the effect would be listed  
12 here along with the other two effects, and  
13 that's their interpretation of the research.

14 Q. You're the statistician on -- on this  
15 project. Do you believe that Exhibit 13, the  
16 representations there, is an accurate  
17 representation of what your research  
18 concluded?

19 MR. B. GORDON: Objection; asked  
20 and answered already.

21 THE WITNESS: The rates and the  
22 decreases are accurate and line up with  
23 what's in the paper.

24 MR. B. GORDON: Same answer you  
25 got last time.

1 ALBRECHT

2 And, Corey, I don't want to cut you  
3 off, you probably got some more left, if --  
4 if you happen to be getting close to a  
5 stopping point, if we're going to quit  
6 anyway --

7 MR. C. GORDON: Yeah, let --

8 MR. B. GORDON: -- this would  
9 allow me to make my flight. It's up to you.

10 MR. C. GORDON: I'm going to do  
11 one more thing, because I did promise you I  
12 would do that.

13 (Whereupon, Exhibit 14 was  
14 marked for identification.)

15 BY MR. C. GORDON:

16 Q. I'm going to show you Exhibit 14. And can  
17 you -- can you identify the person on the  
18 left in the --

19 A. Yeah.

20 Q. -- what look like surgical scrubs?

21 A. Yeah, Reed.

22 Q. That's Dr. Mike Reed?

23 A. Yes.

24 Q. Do you know any of the other people in the  
25 picture?

1 ALBRECHT

2 A. Not off the top of my head.

3 Q. And you were -- you were at Dr. Reed's  
4 hospital in England, right?

5 A. Yes, I was.

6 Q. Okay. Do you see that chart on the wall  
7 there behind -- behind these four people?

8 A. Yeah, I can roughly make it out.

9 Q. Can you --

10 A. Yup.

11 Q. Can you -- even with my old tired eyes it  
12 looks like --

13 A. Yeah, no, I'm reading it.

14 Q. -- "Trust wide surgical site infection  
15 intervention timeline for orthopedic lower  
16 limb surgery combined." Do you see that?

17 A. Yes, I do.

18 Q. Do you recall seeing that chart or anything  
19 like that either on the wall when you were  
20 there or in printed form?

21 A. I don't recall. I don't recall.

22 Q. Okay.

23 A. I wasn't looking for it if I had.

24 Q. Okay. And would that -- well, strike that.

25 Do you see that -- that blue line

1 ALBRECHT

2 that goes down, up a little bit --

3 A. I do.

4 Q. -- and then goes down? Would you agree that  
5 that conveys more information about what  
6 might have been happening in terms of SSI  
7 trends than an average -- an arithmetic mean  
8 average of SSI rates over whatever that time  
9 period is?

10 MR. B. GORDON: I'm going to  
11 object to the fact that you can't read  
12 anything on this except for the very first  
13 top line. I have no idea what you're talking  
14 about.

15 THE WITNESS: I understand the  
16 trendline and the series of events that  
17 follow with it that are showing on the graph.  
18 And from a graphic like this, one can look at  
19 a trendline from their eye on the top, it's  
20 hard to see on the bottom what's going on,  
21 though, in terms of the data.

22 I don't know. If you group  
23 everything at a very small granular level,  
24 things get kind of wonky too up and down. I  
25 think that adding to this paper those other



1 ALBRECHT

2 two effects would be reasonable, but other  
3 than that, I don't know if I would change  
4 anything based on that.

5 BY MR. C. GORDON:

6 Q. Well, I -- and I -- to Mr. Ben Gordon's  
7 point, you can't tell what those  
8 interventions --

9 A. It's observational data too. None of these  
10 are tested interventions. And because the  
11 rate went down may not be due to the fact  
12 that that happened there, and that's the  
13 devil of the details with these kind of  
14 things, they're observational. You don't  
15 know if that did it or something else, so,  
16 really, you need that randomized trial. And  
17 this data suffers from the same problem, it  
18 is observational. It is not controlled in a  
19 randomized trial.

20 Q. When did you first meet Andrew Legg?

21 A. It would have had to have been in the UK when  
22 I was there. I don't think he was stateside  
23 when I first met him. I think it was  
24 correspondence by e-mail maybe.

25 Q. How did you first get in touch with him?

1 ALBRECHT

2 A. Similar to McGovern and Paul, I'm sure it  
3 would be that same channel. So it was either  
4 through Scott Augustine, maybe David Leaper.  
5 I'm not sure who kind of hooked us up.

6 Q. And you went to Sheffield where --

7 A. Yes.

8 Q. -- where he was, right?

9 A. Uh-huh. Yes.

10 Q. And you met Dr. Hamer as well?

11 A. Yes. I don't remember if I shook his hand or  
12 if I just met him over e-mails.

13 Q. Okay. But you and Legg collaborated on -- on  
14 research involving forced-air warming?

15 A. We did. I was not a listed author in those  
16 studies.

17 Q. And by, "Those studies," I just want to be  
18 clear, there's Legg and Hamer, and then  
19 there's Legg, Cannon and Hamer.

20 A. Yes.

21 Q. You collaborated on both of those, right?

22 A. I collaborated, I believe, on one of the two.  
23 You'd have to show me the studies so I can  
24 look at the setup on them, if you have them.  
25 I could tell you then which elements I was

1 ALBRECHT

2 involved in and not. We did provide them  
3 with some research materials.

4 Q. And -- in the interest of time, I'm not going  
5 to looking for them so we can delay this, but  
6 did the -- well, strike that.

7 MR. C. GORDON: We'll suspend for  
8 now.

9 MR. B. GORDON: Okay. We're going  
10 to reserve questions for another day. Thank  
11 you very much.

12 MR. C. GORDON: Do you want to try  
13 and schedule now or --

14 THE WITNESS: Yeah, I think now  
15 would be best just so we know.

16 THE VIDEOGRAPHER: We're going off  
17 the record at 3:11 p.m.

18 (Whereupon, the foregoing  
19 deposition adjourned at 3:11 p.m.)  
20  
21  
22  
23  
24  
25

## DEPOSITION CORRECTION SHEET

TITLE: In Re: Bair Hugger Forced Air Warming  
Products Liability Litigation

WITNESS: Mark Albrecht

PAGE	LINE	DESIRED CHANGE
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1  
2  
3 I, Mark Albrecht, have read this  
4 deposition transcript and acknowledge  
5 herein its accuracy except as noted:  
6

7 \_\_\_\_\_  
8 Witness Signature  
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1 STATE OF MINNESOTA )  
 ) ss  
2 COUNTY OF ANOKA )  
3

4 Be it known that I took the foregoing  
deposition of Mark Albrecht, Volume 1, on  
October 7th, 2016, in Minneapolis, Minnesota;  
5

6 That I was then and there a notary public  
in and for the County of Anoka, State of Minnesota,  
and that by virtue thereof, I was duly authorized  
7 to administer an oath;

8 That the witness was by me first duly  
sworn to testify to the truth, the whole truth and  
9 nothing but the truth relative to said cause;

10 That the foregoing transcript is a true  
and correct transcript of my stenographic notes in  
11 said matter;

12 That the witness reserved the right to  
read and sign the transcript;  
13

14 That I am not related to any of the  
parties hereto, nor interested in the outcome of  
the action;  
15

16 WITNESS MY HAND AND SEAL this 19th day of  
October, 2016.  
17  
18

---

19 Amy L. Larson, RPR  
My Commission Expires 1/31/2020  
20  
21  
22  
23  
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25

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

-----  
In Re:  
Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

All Actions MDL No.  
15-2666 (JNE/FLM)  
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VIDEOTAPED DEPOSITION

OF

MARK ALBRECHT

VOLUME 2

Minneapolis, Minnesota

Saturday, November 12th, 2016  
-----

Reported by:  
Amy L. Larson, RPR  
Job No. 115236

ALBRECHT

APPEARANCES:

ON BEHALF OF 3M:

COREY GORDON, ESQUIRE

PETER GOSS, ESQUIRE

BLACKWELL BURKE

431 South Seventh Street

Minneapolis, MN 55415

FOR THE PLAINTIFF:

GABRIEL ASSAAD, ESQUIRE

KENNEDY HODGES

4409 Montrose Boulevard

Houston, TX 77006

GENEVIEVE ZIMMERMAN, ESQUIRE

MESHBESHER & SPENCE

1616 Park Avenue South

Minneapolis, MN 55404

ALSO PRESENT: Kraig Hildahl, Videographer



## ALBRECHT

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1 ALBRECHT

2 THE VIDEOTAPED DEPOSITION OF MARK ALBRECHT,  
3 VOLUME 2, taken on this 12th day of November,  
4 2016, at the Law Offices of Blackwell, Burke, LLP,  
5 431 South Seventh Street, Suite 2500, Minneapolis,  
6 Minnesota, commencing at approximately 9:05 a.m.

7  
8 P R O C E E D I N G S

9  
10 THE VIDEOGRAPHER: We're on the  
11 record. This is the start of tape labeled  
12 number 1, volume 2 of the videotaped  
13 deposition of Mark Albrecht In the Matter of  
14 In Re: Bair Hugger Forced Air Warming  
15 Products Liability Litigation filed in the  
16 U.S. District Court for the District of  
17 Minnesota, case number 15-2666 (JNE/FLN).

18 This deposition is being held at  
19 Blackwell & Burke Law Firm in Minneapolis,  
20 Minnesota on November 12th, 2016. The time  
21 is 9:06 a.m. My name is Kraig Hildahl, I'm  
22 the legal video specialist from TSG  
23 Reporting, Incorporated. The court reporter  
24 is Amy Larson also in association with  
25 TSG Reporting.

1 ALBRECHT

2 Will counsel please introduce  
3 themselves for the record.

4 MR. ASSAAD: Gabriel Assaad on  
5 behalf of the plaintiff.

6 MS. ZIMMERMAN: Genevieve  
7 Zimmerman for the plaintiffs.

8 MR. COREY GORDON: Corey Gordon  
9 for the defendants.

10 MR. GOSS: Peter Goss for the  
11 defendants.

12 MR. COREY GORDON: Okay.

13 THE VIDEOGRAPHER: Will the court  
14 reporter please swear in the witness and then  
15 we can begin.

16 MR. COREY GORDON: Well, he's  
17 been -- he's still sworn in, but go ahead.

18  
19 MARK ALBRECHT,  
20 a witness in the above-entitled action,  
21 after having been first duly sworn, was  
22 deposed and says as follows:  
23  
24  
25

1 ALBRECHT

2 EXAMINATION

3 BY MR. COREY GORDON:

4 Q. Good morning, Mr. Albrecht.

5 A. Hello.

6 Q. We're going to finish up your deposition that  
7 we started a couple of weeks ago.

8 A. Okay.

9 Q. Let me start out by showing you two documents  
10 that I've marked as Exhibits 15 and 16.

11 A. Okay.

12 (Whereupon, Exhibit 15 and  
13 Exhibit 16 was marked for  
14 identification.)

15 BY MR. COREY GORDON:

16 Q. And could you just briefly tell -- tell us  
17 what these two documents represent?

18 A. Yeah. These are an agreement between myself  
19 and the employer for funding graduate school.  
20 One is for an MBA at the Carlson Business  
21 School, and the other is for a Ph.D. program,  
22 but we ended up rolling that to be a master's  
23 in statistics instead.

24 Q. So the dollar figures in Exhibit 16 that  
25 refer to the Ph.D. program, year one, year

1 ALBRECHT

2 two, year three --

3 A. Yup.

4 Q. -- how did that change when you changed to a  
5 master's in statistics?

6 A. It was similar. I think the all-in cost for  
7 the master's came 20 to \$25,000. I think it  
8 was 20,000.

9 Q. Okay. And that was Augustine Biomedical that  
10 was agreeing to pay for your graduate  
11 program?

12 A. Yup, and they did.

13 (Whereupon, Exhibit 17 was  
14 marked for identification.)

15 BY MR. COREY GORDON:

16 Q. And then I'm going to show you Exhibit 17,  
17 and this is a document from -- is that  
18 March 1st, 2012?

19 A. That looks correct.

20 Q. Okay. And this -- the promissory notes that  
21 Exhibit 17 refers to, those would be  
22 Exhibits 15 and 16; is that correct?

23 A. That looks correct, although, this one here  
24 for the Ph.D. program, I do not recall if we  
25 made a different set.

1 ALBRECHT

2 Q. Okay. If you -- if you had made a different  
3 set, would that have been something you still  
4 would have had copies of?

5 A. Yeah. And I -- that's true, I would have  
6 submitted all that, so this must be it.

7 Q. Well, I might have missed it too. I was  
8 noticing that sequentially in your Bates  
9 numbers there seems to be a -- I don't have  
10 Bates number 10.

11 But in any event, just tell -- tell  
12 me the circumstances under which the  
13 Exhibit 17 came into being, why -- why was  
14 this --

15 A. So why did I resign?

16 Q. Well, is -- so -- well, I guess maybe that's  
17 the answer. This was prompted by your  
18 resigning from Augustine Biomedical?

19 A. I did resign, yes.

20 Q. Okay. And when was that?

21 A. It should have been the date on the document,  
22 I would imagine. So 3/1/12, thereabouts,  
23 maybe a week before or two.

24 Q. And why did you resign?

25 A. They had cut our pay. They were on hard



1 ALBRECHT

2 times and I had to go find gainful employment  
3 elsewhere.

4 Q. Okay. Now, looking back at Exhibits 16 -- 15  
5 and 16, it looks -- there's -- in each case  
6 there's a paragraph 10 that refers to  
7 termination as a result of reduction in force  
8 unrelated to causes --

9 A. Uh-huh.

10 Q. -- and then the amounts are being forgiven.  
11 So was your -- your -- your leaving in 2012,  
12 was that considered a reduction in force or  
13 just a voluntary --

14 A. It was -- I never had employment more  
15 involved, but we went from 40 hours a week to  
16 32 being paid, so that probably doesn't  
17 constitute, although I don't know, I am not  
18 an employment lawyer.

19 Instead, we thought, or at least I  
20 thought, that it would be easier to work out  
21 an agreement, and so the MBA business loan,  
22 I've been there long enough that that was  
23 forgiven.

24 And then the outstanding for the  
25 \$21,000 that you see here for the master's

ALBRECHT

program, that was still on the table, so to speak, and so we worked out something that worked for both parties.

Q. And the -- the workout for you to repay the -- the value of the 21,000 or so, is set forth in paragraph 5 of Exhibit 17; is that right?

A. Correct.

Q. And that was for you to complete the successful application of three research projects; is that right?

A. Yes.

Q. And one was -- the first one was the Belani that was at that time under review by the Anesthesia & Analgesia Journal?

A. Correct.

Q. And that -- that you had published?

A. I believe so, yes.

Q. The second one was the Reed, et al., published -- being reviewed by the AANA Journal, right?

A. Yup.

Q. And that also got published?

A. It did.

ALBRECHT

Q. But the third one is something that -- strike that.

The third one is -- references an article by Barnett, et al., that reports deep joint infection from Ridgeview Hospital in Waconia?

A. Uh-huh.

Q. Did that ever get published?

A. It never ever really got constructed, so that was something where the employer thought about doing this and had discussed some agreements with some physicians. I wasn't that deeply involved in this one. And just it never really came to be.

Q. Okay. So where it says, "The data needs to be compiled and analyzed," as far as you know you -- well, from -- you weren't involved in actually compiling or analyzing any data then from --

A. Not for this direct study that's listed here. I did update, for example, some of the infection data, as you've seen in e-mails, after my time there.

Q. You're talking about the McGovern study?

1 ALBRECHT

2 A. Yeah, the one that we had talked about last  
3 time. So augmenting the data, for example,  
4 things like that.

5 Q. And we'll talk about that in more detail.

6 But other than this reference to --  
7 in Exhibit 17 to this Barnett, et al.,  
8 Ridgeview Hospital, have you -- do you recall  
9 any other discussions or involvement in  
10 anything related to that project?

11 A. If it's defined as something else, I don't  
12 know, this is a while ago. My memory on  
13 stuff like this where it doesn't get  
14 executed, put into a publication, I have a  
15 hard time giving anything that's really  
16 accurate here. If we have some documents  
17 that we could look at, maybe I could help you  
18 out. I don't know if you have anything.

19 Q. Well, we'll see if anything relates to that.  
20 Did -- did you have any discussions with --  
21 with Scott Augustine that, you know, Hey,  
22 this Ridgeview project never went anywhere,  
23 so instead of that I'll do this or --

24 A. I've given him help analyzing other data and  
25 completing other data from, for example, Reed

1 ALBRECHT

2 and McGovern at times to kind of compile  
3 statistics. So we've kind of done that in  
4 place flexibly of this Article C.

5 Q. At this point do you consider your  
6 obligations to Augustine Biomedical to be  
7 under the agreement to -- in Exhibit 17, are  
8 those complete now?

9 MR. ASSAAD: Objection to form.

10 THE WITNESS: I don't know. It's  
11 hard to say.

12 BY MR. COREY GORDON:

13 Q. Is it -- well, at this point do you feel --  
14 do you believe you still have any continuing  
15 obligation to Augustine Biomedical to do any  
16 work for them in satisfaction of your  
17 repayment of the promissory notes for your  
18 educational expenses?

19 MR. ASSAAD: Objection to form.

20 THE WITNESS: If asked, I would  
21 have to deal with that bridge at that time.  
22 I -- it's a gray area. I don't know.  
23 Depending on what would be asked.

24 MR. COREY GORDON: Okay.

25 BY MR. COREY GORDON:

1 ALBRECHT

2 Q. Let me show you Exhibit 18.

3 (Whereupon, Exhibit 18 was  
4 marked for identification.)

5 BY MR. COREY GORDON:

6 Q. And if you could help me out here, I'm trying  
7 to understand, this is a -- a conflict of  
8 interest for the Anesthesia & Analgesia  
9 Journal, right?

10 A. Yeah.

11 Q. And it lists the first author as Gauthier.

12 A. Okay.

13 Q. But I'm not sure what that refers to.

14 A. I don't know.

15 Q. If you look at exhibit -- in the pile there's  
16 the exhibits from the last -- the first day  
17 of your deposition, and I think Exhibits 4,  
18 5, 6, 7, 8 and 9 are documents we've  
19 previously marked that you had identified as  
20 publications on which you are identified as a  
21 coauthor.

22 A. Okay.

23 Q. And the only Anesthesia & Analgesia one I see  
24 is Exhibit 7.

25 A. Excuse me. Okay.

1 ALBRECHT

2 Q. So I'm -- was -- is there some other  
3 publication for Anesthesia & Analgesia where  
4 Robert Gauthier was the first author?

5 A. I don't believe so. This may be a form that  
6 was never submitted to the journal too. I'm  
7 unsure where this came from.

8 Q. And the -- the title, "Forced-Air Warming, An  
9 Evaluation of Laminar Operating Room  
10 Ventilation Disruption," I -- again, I don't  
11 see any -- any of the ones that -- that have  
12 been published that has that same title.

13 A. Uh-huh.

14 Q. So you -- but you can't help me out on --  
15 is -- do you -- do you have any recollection  
16 that at one time Dr. Gauthier was going to be  
17 an author on a publication that ended up  
18 being Exhibit 7?

19 MR. ASSAAD: Objection to form,  
20 lack of foundation.

21 THE WITNESS: I don't know. We  
22 have a lot of discussions with physicians  
23 when we're planning these, and sometimes we  
24 start a manuscript and stop it and then we  
25 brand some of the data and put it in

1 ALBRECHT

2 something else and reform it. I have a hard  
3 time answering that, I'm unsure.

4 MR. COREY GORDON: Okay.

5 (Whereupon, Exhibit 19 was  
6 marked for identification.)

7 BY MR. COREY GORDON:

8 Q. Now I'll show you Exhibit 19. This is a  
9 series of e-mails back and forth between you  
10 and Christopher Nachtsheim; is that right?

11 A. It looks that way.

12 Q. And he -- he was a professor of yours at the  
13 University of Minnesota; is that right?

14 A. He was.

15 Q. And these look like they're all taking place  
16 in February or so of 2012. Is that -- were  
17 you a student at that time?

18 A. Probably not. I probably graduated at that  
19 time.

20 Q. Okay. And this is -- it's just a little bit  
21 before the -- the March promissory note  
22 document that we looked at before, but it  
23 appears that -- from this that you were  
24 already gone from Augustine Biomedical; is  
25 that right?



ALBRECHT

A. No. 3M had given me a job offer in a staff-related position. I had explained to the folks all my conflicts upfront, and they were going to extend the offer and they even told me to put in your two weeks, and I said, nope, I'm going to wait for your legal to clear, and thank God I did that.

Q. So you were still employed by Augustine as of --

A. Yeah.

Q. -- March 14th, 2012?

A. Yup.

Q. Okay. And Dr. Nachtsheim, or Professor Nachtsheim, says -- said to you in the middle of the first page, "I'm presuming you couldn't get the noncompete removed by Scott"; do you see that?

A. Uh-huh.

Q. What was that a reference to?

A. My current -- it was a reference to the 3M lawyers reviewing my noncompete with Augustine and decided that they didn't want to take on any of the legal challenges of having me work in that organization.

1 ALBRECHT

2 Q. But what -- what -- what's your -- what was  
3 your understanding of what the noncompete  
4 referred to?

5 A. Patient-warming products.

6 Q. Okay. Are you -- I mean, I'm sorry, maybe  
7 I'm being obtuse.

8 Are -- did you -- do you understand  
9 that there was some contractual obligation  
10 that you had to Augustine that precluded you  
11 from doing certain work that could  
12 potentially be competitive with what --

13 A. Yeah.

14 Q. -- you had done when you were there?

15 A. Oh, absolutely.

16 MR. ASSAAD: Objection to form.

17 MR. COREY GORDON: Okay.

18 BY MR. COREY GORDON:

19 Q. And when -- when you say to Professor  
20 Nachtsheim, "No, he wouldn't go for that, I'm  
21 as certain about that as I am about death and  
22 taxes," was that referring to the noncompete?

23 A. Yes.

24 Q. And why were you certain that he would not  
25 remove the noncompete?

1 ALBRECHT

2 A. It's speculation on my part. I never asked  
3 him. I don't know. I was in a place of  
4 frustration with this e-mail. I got offered  
5 a board job that was in a Six Sigma group  
6 that had no relation to patient warming, and  
7 they were okay with me not working on patient  
8 warming or any related products for the  
9 duration of my noncompete, and we had talked  
10 about that during my interview. So all the  
11 parties thought this shouldn't be an issue.  
12 I was told by the internal 3M folks that,  
13 Hey, we don't see this is going to be an  
14 issue at all, yet it was. So here is a  
15 little frustration that's captured in the  
16 e-mail.

17 Q. And even though you were -- it was a  
18 completely unrelated at a part of 3M that had  
19 nothing to do with patient warming --

20 A. I believe that, yes.

21 Q. -- you were certain that Scott Augustine  
22 would not agree to waive the noncompete  
23 agreement to allow you to work for 3M?

24 MR. ASSAAD: Objection to form,  
25 misstates prior testimony.

1 ALBRECHT

2 THE WITNESS: I don't know. I  
3 never asked him. Again, this is me venting.

4 MR. COREY GORDON: Okay.

5 THE WITNESS: That's speculation  
6 on my part.

7 (Whereupon, Exhibit 20 was  
8 marked for identification.)

9 BY MR. COREY GORDON:

10 Q. Let me show you Exhibit 20. This is an  
11 e-mail -- well, I guess it looks like a  
12 couple of e-mails to you from Paul McGovern;  
13 is that right?

14 A. It appears that way.

15 Q. And Paul McGovern would be the -- the first  
16 author on the McGovern study that we  
17 previously marked as Exhibit 8; is that  
18 right?

19 A. Yes.

20 Q. Now, in the first e-mail, the one from  
21 February 21st at 5:52 p.m., you told  
22 Dr. McGovern that you had accepted a job at  
23 the National Marrow Donor Program; is that  
24 right?

25 A. Yes.

ALBRECHT

Q. This was roughly a week or so after the exchange with Nachtsheim that we just talked about that -- after you had learned that you couldn't take the job at 3M because of the noncompete; is that right?

A. Say that one more time. I was just reading this, I was distracted.

Q. That's okay.

This is just -- this is about a week after the Nachtsheim e-mail where you had --

A. Yeah.

Q. -- you were venting, as you said. So in that intervening week apparently you got the job at the National Marrow --

A. I continued the job search and circled back to when I had shut down, yeah.

Q. Now, at the very -- very bottom of your -- the first e-mail on Exhibit 20, you say to Dr. McGovern, "Also, you don't know the company I accepted an offer with, if Scott asks, just said I took a bioinformatics person. I can't share that information until I start or I risk him placing an angry phone call trying to spoil it. Trust me, it's not

ALBRECHT

above him."

Why did you ask Dr. McGovern not to tell Scott Augustine where you had accepted an offer if he talked to him?

A. Because the offer hadn't gone through yet and I didn't have all the pieces in place where I had signed an offer letter.

Q. Well, why did you think that there was a risk that Scott Augustine would place an angry phone call to spoil it?

A. Well, you know, at this time we have yet to have gone through any of resolving promissory notes or details like that, so -- you know, again, this probably could have been done with a little more tact, but this is a personal communication that's intended to be private, yet, they never are when you do this, I'm learning that.

Again, it's speculation on my part. I just -- there were some things hanging over my head with this, there were some conflicts that Scott obviously wouldn't want me to leave, and there were some pieces in play, as you show here, in terms of agreements that

1 ALBRECHT

2 were made that I have to rework, so that's  
3 what that was about.

4 Q. Now, apparently, Dr. McGovern had provided a  
5 reference for you for your --

6 A. He did.

7 Q. -- job search?

8 And he -- in this exchange of  
9 e-mails on Exhibit 20, he asked you if  
10 Scott Augustine was aware that Dr. McGovern  
11 had provided a reference for you, right?

12 A. No, I did not tell Scott that McGovern  
13 provided a reference at that time.

14 Q. Right. And Dr. McGovern was asking you if  
15 you had told Scott -- or if Scott was aware  
16 that Dr. McGovern had provided a reference  
17 for you?

18 A. He did ask, yes.

19 Q. And you told him that Scott did not know that  
20 Dr. McGovern provided a reference and you  
21 asked Dr. McGovern to, "Just play dumb"?

22 A. Yeah, those are the words there.

23 Q. Why did you not want Dr. McGovern to disclose  
24 to Dr. Augustine that he had provided a job  
25 reference for you?

1 ALBRECHT

2 A. Because I had not yet accepted an offer and  
3 things are still at risk.

4 Q. And what was it that you thought was at risk?

5 A. You don't want your current employer to know  
6 that you're looking for a job until you've  
7 accepted one, so that's what I think is a  
8 risk. You risk losing your job.

9 And, again, this is a little  
10 frustration, venting too, in these e-mails,  
11 and it's not as tactful as I could be.

12 Q. Were you afraid that Dr. Augustine would be  
13 vindictive?

14 MR. ASSAAD: Objection to form,  
15 calls for speculation.

16 THE WITNESS: No, it didn't turn  
17 out to be that way, he was very reasonable.  
18 And when you haven't dealt with something,  
19 you assume the worse. And we actually were  
20 able to come to an amicable agreement.

21 MR. COREY GORDON: Okay.

22 (Whereupon, Exhibit 21 was  
23 marked for identification.)

24 BY MR. COREY GORDON:

25 Q. I'll show you Exhibit 21. The very top



1 ALBRECHT

2 e-mail is to a TAA [sic] Albrecht. Who is  
3 that?

4 A. That is my brother Tom, it looks like.

5 Q. Okay. Okay. And what does the subject line  
6 mean, "Well, let's see if the fish bites on  
7 this, although I'm not sure I want to do the  
8 work even for big," dollar sign dollar sign?

9 A. Let me read through the e-mail first --

10 Q. Sure.

11 A. -- and then I will comment on that, please.  
12 (Reviews document.)

13 Honestly, I'm not sure what I meant  
14 by that.

15 Q. Okay. Well, at the time of -- well, at least  
16 as of May 2012, you were already gone from  
17 Augustine, right?

18 A. That would appear to be correct.

19 Q. And you had already worked out the deal on  
20 the promissory note --

21 A. Yup.

22 Q. -- correct?

23 So if you look at the earlier  
24 e-mails, there's -- there's -- there's an  
25 exchange between you and Dr. Mike Reed, one

1 ALBRECHT

2 of the coauthors on a couple of the papers,  
3 right?

4 A. Correct.

5 Q. And the more recent one from Reed May 19th,  
6 2012, to you with a carbon copy to  
7 Scott Augustine asks for your help in seeing  
8 if there's been any change in the -- since --  
9 in the data you examined, the McGovern study,  
10 the Exhibit 8, right?

11 A. Uh-huh.

12 Q. And this -- and Dr. Augustine forwarded this  
13 to you and was asking you if you could help  
14 out in analyzing the additional data,  
15 correct?

16 MR. ASSAAD: Object to the form of  
17 the last question.

18 BY MR. COREY GORDON:

19 Q. You know, actually, I'm going to withdraw it  
20 and -- because I realize it was probably a  
21 little bit confusing without this.

22 (Whereupon, Exhibit 22 was  
23 marked for identification.)

24 BY MR. COREY GORDON:

25 Q. Let me show you Exhibit 22. And the -- much

1 ALBRECHT

2 of the earlier e-mail chain is the same, but  
3 on Exhibit 22 if you look at -- in the middle  
4 of the first page there's a -- a May 4th,  
5 2012, e-mail from Augustine to you asking  
6 you, "How much are you charging for a day's  
7 work"; do you see that?

8 A. Say that one more time. Sorry. Okay, "Mark,  
9 How much are you charging for a day's work,"  
10 got it.

11 Q. And if you look below that, it looks like  
12 it's essentially the same or a good part of  
13 the same e-mail chain in Exhibit 21?

14 A. Yes, it does.

15 Q. And you had -- well, strike that.

16 So Dr. Augustine -- it was your  
17 understanding that Dr. Augustine was asking  
18 you to do some additional work on the more  
19 recent Reed/McGovern data, correct?

20 A. Yup.

21 MR. ASSAAD: Objection to the  
22 form.

23 BY MR. COREY GORDON:

24 Q. And you forwarded this to your brother at --  
25 on the same day at about, well, three minutes

1 ALBRECHT

2 after you got it from Dr. Augustine. The  
3 subject line on that is, "Hook, line and  
4 sinker," right?

5 A. Correct.

6 Q. What did you mean by, "Hook, line and  
7 sinker"?

8 MR. ASSAAD: Objection to form.

9 THE WITNESS: That the work was  
10 available, it looks like.

11 BY MR. COREY GORDON:

12 Q. And why -- what does, "Hook line and sinker,"  
13 mean?

14 A. It means that you'd have an ability to catch  
15 a fish and charge consulting dollars.

16 Q. Okay. And your brother's response to this in  
17 Exhibit 22 was, "Thinking of reeling it in or  
18 is this more of a catch and release day for  
19 you"?

20 A. Uh-huh.

21 Q. What did you understand him to mean by that?

22 MR. ASSAAD: Objection; calls for  
23 speculation.

24 THE WITNESS: Do you want the work  
25 or not.

1 ALBRECHT

2 BY MR. COREY GORDON:

3 Q. And your response was to say, "Sadly, I'm not  
4 sure." And you say you're thinking of  
5 charging a higher rate, and, "If he goes for  
6 it fine, if not, whatever," right?

7 A. Yeah, I see that.

8 Q. And then you go on to say, "The only problem  
9 is that I don't trust him to pay me."

10 A. Uh-huh.

11 Q. Why did you not trust him to pay you?

12 A. Because when I left the company, it was  
13 having financial difficulties. So it's not a  
14 statement about him, it's about the state of  
15 the health of the company.

16 Q. So you were concerned that the company was in  
17 such dire financial straits that you might  
18 not end up getting paid for your work --

19 MR. ASSAAD: Objection to form.

20 BY MR. COREY GORDON:

21 Q. -- is that right?

22 MR. ASSAAD: Objection to form.

23 THE WITNESS: I don't know.

24 Again, I didn't have access to all that, but  
25 they did cut our hours.

1 ALBRECHT

2 (Whereupon, Exhibit 23 was  
3 marked for identification.)

4 BY MR. COREY GORDON:

5 Q. I'll show you Exhibit 23. The very top part  
6 of this is an e-mail exchange -- or an  
7 e-mail -- well, e-mail exchange between you  
8 and Dr. McGovern; is that correct?

9 A. Yes, it is.

10 Q. And could you just generally summarize what  
11 the -- the general back and forth of this  
12 e-mail chain refers to?

13 A. Maybe you could help ask what you're looking  
14 for a little more clearly.

15 Q. Well, you recall that there was a -- a study  
16 that -- in which a Dr. Dan Sessler was one of  
17 the coauthors that addressed some of the  
18 issues related to the use of forced-air  
19 warming in laminar airflow rooms?

20 A. In a different viewpoint, yes.

21 Q. And there was -- and Scott Augustine was not  
22 happy about that, right?

23 A. In this e-mail here, he appears not to be.

24 Q. Is this -- do you recall independently of  
25 this e-mail that Dr. Augustine was upset

ALBRECHT

about the Sessler study?

A. Upset is not the correct word, I don't think. I think he didn't agree with the methods in the data.

Q. Well, you said to Dr. McGovern in Exhibit 23 that, "The letter Scott sent is disturbing," right?

A. I did.

Q. What did you mean by disturbing?

A. It's an open research community, people are allowed to have a disagreeing opinion. I sometimes think he can take it a little too far.

Q. In fact, you went on to say, "He keeps attack" -- "attacking these people without cause," right?

A. I do.

Q. What -- what attack was he -- were you referring to?

A. Well, down in the e-mail below.

Q. The one that you just moments ago described as a difference of opinion and methodology?

A. Statements like, "Nonetheless, we will continue to publicly call it fraud," things

ALBRECHT

like that seem a little over the top.

Q. Okay. And, in fact, Dr. Augustine was accusing Dr. Sessler of committing scientific fraud, right?

A. Those are his words, not mine. I'm not able to make that statement.

Q. Well, in this e-mail to Dr. McGovern you said, "Calling someone a fraud in public is not something to take lightly, particularly since it is just a disagreement in research opinion," right?

A. That is my opinion, possibly, of the e-mail, yes.

Q. So as of May 30th -- or May 20th, 2012, isn't it a fact that you were of the view that Dr. Augustine was calling Dr. Sessler a fraud in public?

A. This was an internal communication between myself and Paul. Scott Augustine is a controversial figure and he does push some buttons. I may have a little bit of hyperbole here, because this isn't in public necessarily, this is a closed discussion between a couple of individuals.



1 ALBRECHT

2 Q. One of those individuals is somebody whose  
3 done a lot of -- or been involved in a lot of  
4 research funded by Dr. Augustine, right?

5 MR. ASSAAD: Objection. Object to  
6 the form.

7 THE WITNESS: In the past I'm  
8 aware that, yes, he has been funded by  
9 Dr. Augustine's companies that he's worked  
10 for.

11 MR. COREY GORDON: Okay.

12 BY MR. COREY GORDON:

13 Q. And when you say it was a confidential  
14 communication, you and Dr. McGovern had  
15 developed a friendship by this point, right?

16 A. A rapport, yes.

17 Q. Okay. Well, and that's why you were able to  
18 ask him to not disclose to Dr. Augustine what  
19 your new job was or to confide -- or to share  
20 with Dr. Augustine that he had given you a  
21 reference?

22 A. He was a professional colleague --

23 MR. ASSAAD: Objection to form.

24 THE WITNESS: -- Dr. McGovern.

25 MR. COREY GORDON: Okay.

1 ALBRECHT

2 BY MR. COREY GORDON:

3 Q. One you felt comfortable saying that the  
4 letter Scott sent was disturbing, right?

5 A. My opinion of it is yes, it is disturbing.

6 Q. Okay.

7 (Whereupon, Exhibit 24 was  
8 marked for identification.)

9 BY MR. COREY GORDON:

10 Q. I'll show you Exhibit 24. First of all, who  
11 is Thomas Neils?

12 A. He was a fellow employee I had worked with.

13 Q. At what company?

14 A. Augustine.

15 Q. Was he still as Augustine as of --

16 A. No.

17 Q. Okay. Where was he working in May of 2012?

18 A. Likely Medtronic, I believe.

19 Q. Okay. And on May 16th of 2012, at 2:46, you  
20 sent him a copy of the Augustine e-mail, an  
21 Augustine e-mail talking about the Sessler  
22 study, right?

23 A. I did.

24 Q. And you said that, "By the way, Scott also  
25 copied me on this about two days ago. He

1 ALBRECHT

2 actually sent this to the doctors that do our  
3 research, Mike and Paul. How crazy is this."

4 Did I read that correctly?

5 A. That's what's in the e-mail.

6 Q. Okay. And the Mike and Paul, that refers to  
7 Mike Reed and Paul McGovern; is that correct?

8 A. Correct.

9 Q. And what did you mean by, "Doctors that do  
10 our research"?

11 A. That we had worked with in the past at the  
12 company we had been employed at.

13 Q. Augustine?

14 A. Yes.

15 Q. So when you -- you as a former Augustine  
16 employee were writing to Thomas Neils,  
17 another former Augustine employee, and you  
18 were referring to Dr. Reed and Dr. McGovern  
19 as the doctors that, "Do our research," you  
20 were talking about doctors that do Augustine  
21 research, right?

22 A. We had worked with them in the past, that's  
23 what was meant by that.

24 Q. And by, "We," I just want to make it clear,  
25 it's not you and Mr. Neils, it's Augustine?

1 ALBRECHT

2 A. Mike and Paul have been funded by Augustine  
3 to do research.

4 Q. And when you said, "The doctors that do our  
5 research," you weren't talking in this e-mail  
6 to Mr. Neils about doctors who do research  
7 for you and Mr. Neils, correct?

8 A. No.

9 Q. You were talking about doctors that do  
10 research for Augustine?

11 A. That we had been employed at in the past,  
12 yes.

13 Q. Okay. And what did you mean by, "How crazy  
14 is this"?

15 A. Well, again, this is kind of backdoor  
16 communications, but it's the -- and goes back  
17 to what you asked me before, that I find the  
18 letter a little bit disturbing and we deal  
19 with that. He's a controversial figure.

20 Q. Okay. And what did you understand Mr. Neils  
21 to be saying to you when he said, "Yes, there  
22 will be flames"?

23 A. I can't speculate.

24 MR. ASSAAD: Objection; calls for  
25 speculation.

1 ALBRECHT

2 THE WITNESS: I don't know.

3 BY MR. COREY GORDON:

4 Q. Did you ask him what he meant by that?

5 A. No.

6 (Whereupon, Exhibit 25 was  
7 marked for identification.)

8 BY MR. COREY GORDON:

9 Q. Let me show you Exhibit 25. This is a  
10 document that was produced by you. It bears  
11 Bates numbers Albrecht\_003353 [sic] through  
12 0003361, and it has -- the title is, "A  
13 Critical Analysis of Forced-Air Warming Does  
14 Not Worsen Air Quality in Laminar Flow  
15 Operating Rooms," by Sessler et al., and the  
16 author appears to be Scott Augustine, M.D.

17 My first question is: Did you have  
18 anything to do with the drafting of this?

19 A. I'm unsure.

20 Q. Is it possible that you did?

21 A. Maybe elements of this, I don't know.

22 Q. Do you recall doing any work to analyze the  
23 Sessler study that's referred to in this in  
24 providing Dr. Augustine with your analysis of  
25 it?

1 ALBRECHT

2 A. I may have. I'm unsure.

3 Q. Okay. Why don't you look through this --

4 A. There's a lot here.

5 Q. -- document and -- I agree -- see if you can  
6 identify anything that appears to be based in  
7 whole or in part on work you might have done.

8 A. (Reviews document.) Okay.

9 Q. Can you identify any areas that you think you  
10 would have had input in?

11 A. He may have asked me for information in  
12 respect to reviewing some of the ventilation  
13 standards possibly. It looks like some of  
14 the results of a couple of the studies  
15 here -- excuse me -- were a part of that.

16 Q. Let me direct you to the page that's marked  
17 at the bottom Albrecht\_0003360.

18 A. Okay.

19 Q. Under the section, "Discussion," do you see  
20 that?

21 A. Yup.

22 Q. There's -- the first study that is discussed  
23 is the McGovern study that's -- we previously  
24 marked as Exhibit 8, correct?

25 A. I believe so.

1 ALBRECHT

2 Q. Okay. And it talks about the -- the -- the  
3 part of the study addressing airflow  
4 ventilation disruption, but then in the next  
5 paragraph Dr. Augustine writes, "More  
6 important, forced-air warming was shown to  
7 cause a 3.8 times increase in deep joint  
8 infection rates." Did I read that correctly?

9 A. Okay.

10 Q. You would agree that the -- that the McGovern  
11 paper in which you were a coauthor, it did  
12 not show that forced-air warming caused a  
13 3.8 times increase in deep joint infection  
14 rates, right?

15 MR. ASSAAD: Objection to form.

16 THE WITNESS: It was an  
17 observational study, so whatever caveats come  
18 with that.

19 BY MR. COREY GORDON:

20 Q. Well, would you agree with Dr. Augustine's  
21 characterization of the study that you were a  
22 coauthor of that it found that forced-air  
23 warming caused a 3.8 times increase in deep  
24 joint infection rates?

25 MR. ASSAAD: Objection to form.

1 ALBRECHT

2 THE WITNESS: It depends on what  
3 you define as "cause." It was associated  
4 with.

5 BY MR. COREY GORDON:

6 Q. In your professional experience as a  
7 statistician dealing in the field of medical  
8 and biological issues, is there any  
9 difference to you between something that's  
10 associated with and something that causes?

11 MR. ASSAAD: Objection to form.

12 THE WITNESS: Yes, there is a  
13 difference between association and cause, and  
14 causation.

15 BY MR. COREY GORDON:

16 Q. And you were one of the coauthors of the  
17 McGovern study that's being characterized  
18 here. Do you agree with the characterization  
19 that your study found that forced-air warming  
20 caused a 3.8 times increase in deep joint  
21 infection rates?

22 MR. ASSAAD: Objection to form.

23 THE WITNESS: I would agree that  
24 it's associated with the 3.8 times increase,  
25 that's what the study would say.



1 ALBRECHT

2 BY MR. COREY GORDON:

3 Q. So you would -- you would -- you would agree,  
4 then, that you did not conclude or show that  
5 it caused a 3.8 times increase in deep joint  
6 infection rates?

7 MR. ASSAAD: Objection to form.

8 THE WITNESS: We did not prove  
9 causation.

10 BY MR. COREY GORDON:

11 Q. So -- and you would agree that this statement  
12 by Dr. Augustine is a mischaracterization of  
13 the study on which you were a coauthor?

14 MR. ASSAAD: Objection to form.

15 BY MR. COREY GORDON:

16 Q. Correct?

17 A. It's speculation, because it didn't use the  
18 exact word "causation." If I were to look  
19 for association versus causation, I'd need to  
20 have that word, if you want me to be frank  
21 with you on statistical terms.

22 Q. I just want you to be frank with me on  
23 whether you think that Dr. Augustine  
24 accurately characterized your study when he  
25 said, "Forced-air warming was shown to cause

1 ALBRECHT

2 a 3.8 times increase in deep joint infection  
3 rates."

4 MR. ASSAAD: Objection to form,  
5 asked and answered.

6 BY MR. COREY GORDON:

7 Q. Is that a correct characterization or not?

8 MR. ASSAAD: Same objection.

9 THE WITNESS: It depends on the  
10 context. It's not causation, it's  
11 association.

12 MR. COREY GORDON: Okay.

13 BY MR. COREY GORDON:

14 Q. I can't give you any more context on what  
15 Dr. Augustine's words are here. "Forced-air  
16 warming was shown to cause a 3.8 times  
17 increase in deep joint infection rates," is  
18 that, in your view as one of the coauthors of  
19 the study, accurate or not accurate?

20 MR. ASSAAD: Objection to the  
21 form, asked and answered. Object to the  
22 preamble.

23 MR. COREY GORDON: But you've got  
24 to move to strike it, Gabriel.

25 MR. ASSAAD: I'm not moving to

1 ALBRECHT

2 strike it, I'm just objecting to it.

3 THE WITNESS: "More importantly,  
4 forced-air warming was shown to associate  
5 with a 3.8 times increase in deep joint  
6 infection rates," that I would agree with.  
7 With what's written there, it seems a  
8 little -- I would have to say probably not,  
9 no.

10 BY MR. COREY GORDON:

11 Q. And -- and, in fact, you recall the exercise  
12 we went through at some length in your first  
13 deposition?

14 A. Oh, yes.

15 Q. The association between forced-air warming  
16 and infection rates maybe would not be very  
17 strong if you factored out the deep vein  
18 thrombosis treatment change?

19 A. If you had reason to believe --

20 MR. ASSAAD: Objection; asked and  
21 answered.

22 THE WITNESS: If you had reason to  
23 believe that the standard of care was lowered  
24 for those patients in those areas, maybe. So  
25 it wasn't no thrombosis agent versus

1 ALBRECHT

2 thrombosis agent, it was different kinds. It  
3 was not no antibiotic versus some antibiotic,  
4 it was different types.

5 BY MR. COREY GORDON:

6 Q. Well, you recall that we went through at some  
7 length at your last deposition and compared a  
8 period of time when the -- when the  
9 Bair Hugger forced-air warming unit was used  
10 with the exact same antibiotic regimen and  
11 the exact same anti-thrombosis --  
12 thromboembolism medication --

13 A. Yup.

14 Q. -- as the HotDog only time period, right?

15 A. Yes.

16 Q. And you agreed that there was no difference  
17 in the rate of infection?

18 MR. ASSAAD: Objection to form,  
19 misstates prior testimony.

20 THE WITNESS: For those periods,  
21 yes.

22 BY MR. COREY GORDON:

23 Q. And, in fact, there was a huge difference  
24 when there was a different drug used for  
25 prevention of deep vein thrombosis during the

1 ALBRECHT

2 Bair Hugger only period?

3 A. I don't know if it was due to that, but it  
4 was associated with that period where it was  
5 the same prophylaxis regimen, okay, on both  
6 terms there wasn't a difference, that's all I  
7 can say on the data.

8 Q. And the period where the -- there was a  
9 seven-month period where the hospital had  
10 switched to a different drug, Xarelto, and  
11 the infection rates during that period were  
12 significantly higher than they were before  
13 and after --

14 MR. ASSAAD: Objection to the  
15 form.

16 BY MR. COREY GORDON:

17 Q. -- right?

18 A. I don't know about before and after, but the  
19 period of higher infection rates were  
20 associated with the use of that drug you talk  
21 about, Xarelto.

22 Q. Okay.

23 A. Not caused, but associated.

24 Q. Right. Okay. Now, who were the -- who would  
25 you describe as the principal people involved

ALBRECHT

in the McGovern study, Exhibit 8? There are seven authors listed.

A. Let me pull it up here. (Reviews document.) Everybody was heavily involved in this one.

Q. Heavily, okay. Did Dr. Belani go to England?

A. He did not.

Q. Okay. Did Dr. Nachtsheim go to England?

A. He did not.

Q. Did Dr. Nachtsheim even know about the study when it was being done?

A. Dr. Nachtsheim commented on the statistics of the study and reviewed them.

Q. Yeah, after it was all done and written up, right?

A. You'll have to define what you mean by "heavy involvement." Dr. Nachtsheim would be for statistical reasons. Different authors provide different perspectives.

Q. Did Dr. Nachtsheim have anything to do with the study -- design of the study before it was commenced?

A. I'm unsure.

Q. Okay. Did Dr. Belani have anything to do with the design of the study before it was

1 ALBRECHT

2 commenced?

3 A. I don't recall.

4 Q. How about Dr. Partington, what was his role?

5 A. He was a surgeon in the UK and was heavily  
6 involved in the manuscript revision process,  
7 if I recall right.

8 Q. When you say, "Heavily involved," what did he  
9 do?

10 A. Himself, Paul and Mike went through -- or I  
11 should say Dr. Reed, Dr. McGovern and  
12 Dr. Partington and Dr. Carluke read through  
13 the study and worked through the clinical  
14 messaging and what the appropriate themes  
15 were based on the data.

16 Q. Okay. Who were the people actually in the  
17 operating room at -- where the bubble part of  
18 the study was done?

19 A. Sure.

20 MR. ASSAAD: Objection to the  
21 form.

22 THE WITNESS: It was myself,  
23 Dr. McGovern, Dr. Reed, I think that  
24 Dr. Partington and Carluke were present for  
25 part of it, if I remember.

1 ALBRECHT

2 BY MR. COREY GORDON:

3 Q. Mr. Albrecht, wouldn't it be correct to say  
4 that you and Dr. McGovern and Dr. Reed were  
5 the principal people involved in designing,  
6 implementing and writing up the study in  
7 Exhibit 8?

8 MR. ASSAAD: Objection to form.

9 THE WITNESS: We contributed in  
10 our different areas. There was quite a bit  
11 of discussion between Partington and Carluke,  
12 if I remember right, so no.

13 BY MR. COREY GORDON:

14 Q. And you think Partington and Carluke were  
15 involved at the early design stages of this?

16 MR. ASSAAD: Objection to form.

17 THE WITNESS: I don't recall,  
18 because a lot of the design happened through  
19 the group talking over in England and  
20 thinking through the issues. These are very  
21 iterative in nature in how they get thought  
22 out and planned.

23 MR. COREY GORDON: Okay.

24 BY MR. COREY GORDON:

25 Q. Let's go back to Exhibit 25 --



1 ALBRECHT

2 A. Okay.

3 Q. -- the same page we were looking at.

4 After the discussion of McGovern's  
5 paper he -- Dr. Augustine writes, "Similar  
6 infection reduction results were found at  
7 Ridgeview Medical Center, Waconia, Minnesota.  
8 These surgeons found that switching from FAW  
9 to air-free HotDog warming reduced their deep  
10 joint infection rate by 81 percent,  
11 1.55 percent of .29 percent"; do you see  
12 that?

13 A. Yeah, I do.

14 Q. Now, the Ridgeview, Waconia, Ridgeview  
15 Medical Center, Waconia, that was one of the  
16 three projects that you had agreed less than  
17 two months before the Exhibit 25 is dated to  
18 review the data and participate in writing up  
19 a publication, right?

20 A. Correct.

21 Q. And that's -- that's the same one that you  
22 say you don't recall ever seeing the data,  
23 correct?

24 A. I may have. It's difficult without some  
25 documentation. It's a long time ago.

1 ALBRECHT

2 Q. So between March 1st when you were -- agreed  
3 as part of your satisfaction of promissory  
4 notes to write up the study on Ridgeview,  
5 Waconia, and April -- this Exhibit 25 dated  
6 April 21st, 2012, where Dr. Augustine cites  
7 an 81 percent reduction in deep joint  
8 infection rates at Ridgeview Medical Center,  
9 Waconia, did you do any analysis of any data  
10 that would have formed the basis of -- of  
11 this 81 percent reduction claim?

12 MR. ASSAAD: Objection to form,  
13 lack of foundation.

14 THE WITNESS: I may have. I don't  
15 know. There are many different data sets we  
16 work with.

17 (Whereupon, Exhibit 26 was  
18 marked for identification.)

19 BY MR. COREY GORDON:

20 Q. I'm going to show you what I've marked as  
21 Exhibit 26. This is -- the front page is  
22 An e-mail exchange between you and  
23 Professor Nachtsheim; is that correct?

24 A. Yes.

25 Q. And in this you are saying, to

1 ALBRECHT

2 Dr. Nachtsheim, "Here is a publication we  
3 will be submitting in a couple of weeks. I'm  
4 currently adding the references, but the  
5 material is done. The abstract will also be  
6 written this week. I'd be thrilled if you'd  
7 like to be a part of this. All you need to  
8 do is take a look at the stats and  
9 conclusions and provide some overview and  
10 guidance. Let me know if you are  
11 interested," right?

12 A. Okay.

13 Q. And the study that you were going to be  
14 submitting in a couple of weeks where the  
15 material was done, that's the McGovern study,  
16 right?

17 A. I'm assuming. I don't know.

18 Q. Well, why don't you --

19 A. I can't tell from this.

20 Q. Why don't you look at the attached e-mail  
21 chain and see if you can figure it out?

22 A. Okay. (Reviews document.) Yup, I would  
23 assume it is that paper.

24 Q. Okay. And, in fact, the title -- or the  
25 subject line, apparently, of the -- this

ALBRECHT

exchange with you and Professor Nachtsheim is, "First publication I'd like to include you on"; is that correct?

A. Yes.

Q. So does this refresh your recollection as to when Professor Nachtsheim became involved in the McGovern paper?

A. In a detailed manner, yes, in terms of looking through the data with a statistical lens.

Q. After it was all done and written up, right?

A. Well, there's still time for revision on this.

Q. But he wasn't involved until you had already done the material and written it up for submission with two -- within two weeks, right?

A. Perhaps.

Q. Now I want to -- oh, before I go to that, have you had any contact with Dr. Scott Augustine since your -- the first day of your deposition?

A. Not to my knowledge.

Q. Have you had any contact with anyone

1 ALBRECHT

2 currently employed by Augustine Biomedical?

3 A. Since the first day of my deposition?

4 Q. Since the first day of your deposition.

5 A. I had a phone call with Andreas just to say I  
6 was being deposed.

7 Q. Andreas Deibel, is it?

8 A. Yes.

9 Q. And what's his role at the company?

10 A. He at the time was running the research and  
11 development arm.

12 Q. Is he still employed by Augustine?

13 A. Yeah, at the time I called.

14 Q. You called him?

15 A. I did.

16 Q. Why did you call him?

17 A. Just to mention I was getting deposed.

18 Q. Oh, this was before your -- the first day of  
19 your deposition?

20 A. Yeah.

21 Q. Okay. You also had an exchange of e-mails  
22 with Dr. Augustine directly before your  
23 deposition, right?

24 A. I believe so.

25 Q. And we'll get to that, I just -- I -- I was

1 ALBRECHT

2 focusing on the time since -- since your --  
3 the first day of your deposition, I just want  
4 to -- it's your testimony that you had no  
5 contact with anybody connected to Augustine?

6 A. Employees with Augustine, no.

7 Q. How about Randy Benham?

8 A. I've not talked to Randy.

9 Q. Now, let's go back to Exhibit 26. And turn  
10 to page -- where at the bottom it's  
11 Bates-stamped Nachtsheim\_0000447.

12 A. Okay.

13 Q. It looks like the top subject line is,  
14 "Infection Data Results"; is that right?

15 A. Yes.

16 Q. And the first part is an e-mail from you to  
17 Dr. Reed with carbon copies to Dr. McGovern,  
18 Professor Nachtsheim, Scott Augustine,  
19 T. Neils and Kumar Belani, right?

20 A. Correct.

21 Q. Why were you sending -- why were you copying  
22 Dr. Augustine on this?

23 A. Because he's a study sponsor, he's paying the  
24 bill.

25 Q. Well, in fact, Dr. Augustine reviewed and

1 ALBRECHT

2 offered editorial input on all of the papers,  
3 right?

4 MR. ASSAAD: Objection to form,  
5 lack of foundation, assumes facts not in  
6 evidence.

7 THE WITNESS: He may have given  
8 his input on some areas.

9 BY MR. COREY GORDON:

10 Q. If you drop down to -- towards the bottom,  
11 there's an e-mail from Dr. Reed to you with a  
12 carbon copy to McGovern, Nachtsheim,  
13 Scott Augustine and T. Neils and Dr. Belani,  
14 right?

15 A. Yup.

16 Q. Okay. And Dr. Reed says, "The trans" --  
17 "transfusion data is unreliable, I'm afraid.  
18 It just shows errors we are making in coding  
19 and billing. It is actually about  
20 10 percent. I can get the reliable data, but  
21 it would take quite a lot of work. Likewise,  
22 I can get ASA grade, but possibly BMI by  
23 pulling the charts/notes. I suggest we don't  
24 do that, as I don't have the resource. What  
25 do others feel?" Did I read that correctly?

1 ALBRECHT

2 A. Yes, you did.

3 Q. What -- what was Dr. Reed -- what did you  
4 understand Dr. Reed to be referring to when  
5 he was talking about transfusion data?

6 MR. ASSAAD: Objection to form.

7 THE WITNESS: This is one of those  
8 outside factors with observational data that  
9 he might want some information about.

10 BY MR. COREY GORDON:

11 Q. What did you understand the ASA grade to  
12 refer to?

13 MR. ASSAAD: Objection to form,  
14 lack of foundation.

15 THE WITNESS: I think that has  
16 something to do with their status prior to  
17 surgery, like how at risk they are, I  
18 believe.

19 BY MR. COREY GORDON:

20 Q. Is that a factor that you would consider in  
21 comparing two groups for surgical site  
22 infection rates?

23 MR. ASSAAD: Objection to form,  
24 lack of foundation, outside the scope.

25 THE WITNESS: Perhaps. I looked



1 ALBRECHT

2 at the clinicians for inclusion/exclusion  
3 criteria for these types of studies to make  
4 determinations on that.

5 MR. COREY GORDON: Oh, okay.

6 BY MR. COREY GORDON:

7 Q. Not your -- not -- not something that you  
8 have the expertise in, is that what you're  
9 saying?

10 A. In some areas, no.

11 Q. Okay. Jump to the next page. Towards the  
12 bottom you say to -- in an e-mail to  
13 Dr. Reed, "Mike, I do agree that it doesn't  
14 make sense for you to chase things when this  
15 is an addition to the paper." Do you see  
16 that?

17 A. Okay.

18 Q. What did you mean by, "This is an addition to  
19 the paper"?

20 A. I don't know.

21 Q. Could it be that the -- the original intent  
22 of the study was the airflow disruption issue  
23 and the bubbles and the looking at the -- the  
24 observational data using surgical site  
25 infection rates was a -- was the addition you

1 ALBRECHT

2 were talking about here?

3 MR. ASSAAD: Objection to form,  
4 calls for speculation, lack of foundation.

5 THE WITNESS: It may have been,  
6 I'm unsure.

7 MR. COREY GORDON: Okay.

8 BY MR. COREY GORDON:

9 Q. And you go on to say that, "You appear to  
10 have reliable data on the following  
11 predictors that might be of interest, COPD,  
12 hypothyroidism, hyperthyroidism,  
13 hypertension, preoperation days stay before  
14 surgery." Did I read that right?

15 A. Yeah.

16 Q. You go on to say, "I think we could make a  
17 case for hypothyroidism and hyperthyroidism  
18 as risk factors, but I'm less sure whether  
19 COPD or hypertension could be seen as  
20 reasonable. What do you think?" And then  
21 you can read the rest of it, but my -- my  
22 question is why would you have any idea  
23 whether COPD or hypertension or  
24 hyperthyroidism or hypothyroidism would be  
25 risk factors?

1 ALBRECHT

2 A. From scanning comparable studies, I'm sure  
3 that's where that comes from. So you look at  
4 the design and the inclusion/exclusion  
5 criteria from other studies, so I'm making a  
6 list here, it looks like.

7 Q. Okay.

8 A. Now, whether or not I'm able to clinically  
9 interpret that is a different story.

10 Q. Now, if you drop down to the -- towards the  
11 bottom of this page, Dr. Reed replies to you  
12 and says, "I agree hypo and hyperthyroidism  
13 and COPD would be useful, but only if the  
14 list was more complete. I think it would  
15 highlight the fact that we don't have ASA  
16 data, obesity and transfusion. We should  
17 leave out." Did I read that correctly?

18 A. Yes, you did.

19 Q. So those are all factors that could impact  
20 the comparative data between two groups,  
21 right?

22 MR. ASSAAD: Objection to form,  
23 lack of foundation.

24 THE WITNESS: It's observational  
25 data. There's many confounders that could be

1 ALBRECHT

2 present and those could be in the list.

3 MR. COREY GORDON: All right.

4 BY MR. COREY GORDON:

5 Q. Well, if you turn to the last page of this --  
6 well, before you get to that, that's -- I  
7 guess the very bottom of the page before,  
8 Dr. Reed wonders "if we should Charlson  
9 score, that is generally what we use when we  
10 analyze this type of data nationally." Do  
11 you see that?

12 A. Okay.

13 Q. Okay. Now, Dr. Reed is the clinician that  
14 you're relying on, right?

15 A. He is.

16 Q. And he's saying, "Let's use the Charlson  
17 score, because that's what they use to  
18 analyze these data nationally," right?

19 MR. ASSAAD: Object to the form.

20 THE WITNESS: Say that one more  
21 time.

22 BY MR. COREY GORDON:

23 Q. Well, Dr. Reed is the clinician you're  
24 relying on for deciding what's an important  
25 comorbidity factor or comparative factor --

1 ALBRECHT

2 A. We're having a discussion back and forth  
3 about what we should think about, yes.

4 Q. Well, you -- you said you relied on the  
5 clinicians, right, because that's not your  
6 area of expertise, right?

7 MR. ASSAAD: Objection to form,  
8 misstates prior testimony.

9 THE WITNESS: In terms of  
10 comparable studies, my area in these studies  
11 is typically to look at other study designs  
12 and see how they compare up, and so I have  
13 some opinion at times on what factors make  
14 sense and what don't, and I have a discussion  
15 with the clinicians about that.

16 MR. COREY GORDON: Okay.

17 BY MR. COREY GORDON:

18 Q. Well, in fact, your reaction to Dr. Reed  
19 suggestion of using the Charlson score was to  
20 say that, "It was an interesting idea, but we  
21 will probably get nicked, because Charlson  
22 score is an validated indicator of mortality  
23 risk, not infection risk," right?

24 A. Okay.

25 Q. And you go on to say, "I think we have enough

1 ALBRECHT

2 given the data collection and accuracy  
3 constraints." Did I read that correctly?

4 MR. ASSAAD: Objection to form.  
5 You did not read that correctly.

6 THE WITNESS: "I think we have  
7 done enough given the data collection and  
8 accuracy constraints."

9 MR. COREY GORDON: I'm sorry, what  
10 did I say?

11 MR. ASSAAD: You said, "I think we  
12 have enough." You forgot the word "done."

13 THE WITNESS: "I think we have  
14 done enough."

15 MR. COREY GORDON: "I think we  
16 have" -- okay. Thank you.

17 THE WITNESS: Those are my words.  
18 BY MR. COREY GORDON:

19 Q. And the data collection and accuracy  
20 constraints, that refers to the inability  
21 either because of resources or availability  
22 of information to collect relevant  
23 comorbidity data --

24 MR. ASSAAD: Objection to form.  
25 BY MR. COREY GORDON:

1 ALBRECHT

2 Q. -- right?

3 A. There were some constraints on what you can  
4 pull in, yes.

5 Q. And the accuracy constraints, what -- what  
6 does that refer to.

7 A. Well, I believe the accuracy constraints were  
8 what were highlighted above, right, "The  
9 transfusion data is unreliable, I'm afraid."

10 Q. Okay.

11 (Whereupon, Exhibit 27 was  
12 marked for identification.)

13 BY MR. COREY GORDON:

14 Q. I'll show you Exhibit 27.

15 A. Okay. Right here, (indicating)?

16 Q. Yes. That's an e-mail from you to -- well,  
17 it's an e-mail exchange between you and  
18 Keith Leland; is that right?

19 A. It appears that way.

20 Q. Who is Keith Leland?

21 A. I used to work with him at Augustine.

22 Q. And as of February 2014, was he still an  
23 employee at Augustine?

24 A. At that time, no.

25 Q. Another member of the Augustine alumni club?

1 ALBRECHT

2 MR. ASSAAD: Objection to form.

3 THE WITNESS: Well, a lot of the  
4 places you work, you do have colleagues that  
5 you've worked with in the past.

6 MR. COREY GORDON: Sure.

7 BY MR. COREY GORDON:

8 Q. And the one thing I just want to ask you  
9 about on this, one you say in the last line  
10 of the first paragraph, "Just stay away from  
11 places with an \$UGUSTIN# in the building  
12 name."

13 A. Okay.

14 Q. What does that refer to?

15 A. There's some shared frustrations we had, I  
16 believe, working there at times.

17 Q. By "there" you mean Augustine?

18 A. Yes.

19 Q. So was -- I'm just -- was this, "\$UGUSTIN#,"  
20 was that a typo or just avoiding typing up  
21 the full -- the full name Augustine?

22 A. I don't know, it's probably me trying to be  
23 clever and funny.

24 Q. So like Voldemort, he who should not be  
25 named?



1 ALBRECHT

2 MR. ASSAAD: Objection to form.

3 THE WITNESS: No, it's just a  
4 joke.

5 MR. COREY GORDON: Okay.

6 BY MR. COREY GORDON:

7 Q. And why were you joking to Mr. Leland that it  
8 would be good to stay away from places with  
9 Augustine in the building name?

10 A. Because we never -- I never had any equity in  
11 the company, he never got material equity in  
12 the company, so that's kind of the reason  
13 why.

14 Q. Let me show you Exhibit 28.

15 (Whereupon, Exhibit 28 was  
16 marked for identification.)

17 BY MR. COREY GORDON:

18 Q. Okay. This is a series of e-mails among  
19 Dr. McGovern, you, Dr. Reed, Scott Augustine,  
20 Brent Augustine, and Professor Nachtsheim,  
21 correct?

22 A. It appears that way.

23 Q. Say that again.

24 A. It appears that way, yes.

25 Q. Okay. First of all, who is Brent Augustine?

1 ALBRECHT

2 A. Scott Augustine's kid.

3 Q. Did he have any involvement in any of the  
4 studies you did?

5 A. I believe he provided some of the graphics.

6 Q. Okay. And do you recall what the British Hip  
7 Society presentation was about?

8 A. Not off the top of my head, no.

9 Q. Let's see if this helps.

10 (Whereupon, Exhibit 29 was  
11 marked for identification.)

12 BY MR. COREY GORDON:

13 Q. I'll show you Exhibit 29 now. This is a  
14 document that at the top says, "Outline of  
15 BHS presentation." Does this appear to be  
16 the British Hip Society presentation referred  
17 to in Exhibit 28?

18 MR. ASSAAD: Objection; calls for  
19 speculation.

20 THE WITNESS: Why don't you give  
21 me a minute to read through this and I'll  
22 look at this and I can tell you.

23 MR. COREY GORDON: That would be  
24 fine. And if you wouldn't mind, let's go off  
25 the record.

1 ALBRECHT

2 MR. ASSAAD: Actually, if he's  
3 going to review it, I want it on the record.

4 MR. COREY GORDON: Well, I need to  
5 go to the bathroom.

6 MR. ASSAAD: Let's go off the  
7 record. Don't review it until we get back on  
8 the record.

9 THE WITNESS: That's fine.

10 MR. COREY GORDON: Wait, wait,  
11 wait, wait, wait, wait a minute.

12 Mr. Assaad, are you representing  
13 him?

14 MR. ASSAAD: No, but he doesn't  
15 have to review anything on his own time. You  
16 have seven hours, and we're already at five  
17 hour -- five-and-a-half hours or six. You  
18 can't ask him to do functioning of a  
19 deposition off the record because you want  
20 more time for your deposition.

21 So he has a choice, he can do  
22 whatever he wants. I'm just saying that he  
23 doesn't have to look at anything off the  
24 record.

25 MR. COREY GORDON: I agree, he has

1 ALBRECHT

2 a choice, he can do whatever he wants and --

3 THE WITNESS: I will be looking at  
4 this on the record.

5 MR. COREY GORDON: That's fine. I  
6 just want to point out, you know, sauce for  
7 the goose, sauce for the gander. You've got  
8 a lot of depositions of our witnesses coming  
9 up, and I can tell you the one that I was  
10 just recently in, documents were reviewed off  
11 the record, lengthy documents. If -- you  
12 know, if the Assaad rule now is that all  
13 things shall be on the record, all reviewing  
14 time shall be on the record, sauce for the  
15 goose, sauce for the gander.

16 THE WITNESS: So are we off the  
17 record here? Are we taking a break?

18 MR. COREY GORDON: You're now off.

19 THE WITNESS: Okay.

20 THE VIDEOGRAPHER: We're going off  
21 the record at 10:30 a.m.

22 (Whereupon, a brief recess  
23 was taken.)

24 THE VIDEOGRAPHER: This is  
25 volume 2, video number 2 in the deposition of

1 ALBRECHT

2 Mark Albrecht. Today is November 12th, 2016.

3 We're going back on the record at 10:42 a.m.

4 THE WITNESS: So where did we  
5 leave off?

6 BY MR. COREY GORDON:

7 Q. Okay. Well, Exhibit 28 is a chain of e-mails  
8 talking about the British Hip Society  
9 presentation, and there was an attachment  
10 to --

11 A. Okay.

12 Q. -- this chain that says, "Outline of BHS  
13 presentation doc." And Exhibit 29 is an  
14 outline of BHS presentation. I'll represent  
15 to you it's my -- my understanding that from  
16 the production from Professor Nachtsheim, and  
17 you can see the -- the numbering that -- it's  
18 something in between, but I believe the  
19 printout of the attachment is Exhibit 29.  
20 But, you know, feel free to look. I just --  
21 there's just a couple of questions I have  
22 about these documents, so --

23 A. All right. Let me skim through it real quick  
24 and I'll be right with you.

25 MR. ASSAAD: Objection to the

1 ALBRECHT

2 preamble, I guess, assumes facts not in  
3 evidence, lack of foundation.

4 THE WITNESS: (Reviews document.)

5 Okay. So I've read the e-mail.

6 MR. COREY GORDON: Okay.

7 THE WITNESS: I have no way to  
8 confirm, but this seems appropriate as the  
9 attachment.

10 MR. COREY GORDON: Okay.

11 BY MR. COREY GORDON:

12 Q. And if you -- on Exhibit 28, if you turn  
13 to -- well, let's go -- let's start with  
14 Exhibit 29 and we'll go back to 28.

15 A. Okay.

16 Q. Exhibit 29, there are a series of comment  
17 boxes on the -- the right-hand side of each  
18 page with initials, and I just want to get  
19 confirmation. It looks like the only sets of  
20 initials are MRR and M; is that right?

21 A. I've got MRR, M2. (Reviews document.) I  
22 think I only see those two.

23 Q. And MRR, that would be Michael R. Reed, or  
24 Mike R. Reed, right?

25 A. I believe so.

1 ALBRECHT

2 Q. And M is you, right?

3 MR. ASSAAD: Objection; lack of  
4 foundation, assumes facts not in evidence.

5 THE WITNESS: I don't know.

6 MR. COREY GORDON: Okay.

7 BY MR. COREY GORDON:

8 Q. Is there --

9 THE WITNESS: It might be.

10 BY MR. COREY GORDON:

11 Q. Well, is there anyone else on the list of  
12 people back and forth whose -- whose comments  
13 might have been offered on the BHS  
14 presentation who has an M as either their  
15 first or last initial?

16 A. No, it does not appear that way.

17 Q. Okay.

18 A. So maybe.

19 Q. All right. Well, let's -- let's take a look  
20 at the -- on Exhibit 29 comment M3 --

21 A. Okay.

22 Q. -- on the first page, bottom of the first  
23 page. So that comment is, "I suggest you add  
24 this as an additional slide to focus the  
25 direction of where you are going in the

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broader context that you are only looking at one potential factor among many possibly culprits."

A. Okay.

Q. "This makes it look impartial and hides our agenda, so to speak," all right?

A. Okay.

Q. Now, if you look back at Exhibit 28 --

A. Okay.

Q. -- on page Nachtsheim\_0000242, in the middle there's an e-mail from you, Mark Albrecht, to Paul McGovern with a cc to Mike Reed, Scott Augustine, Brent Augustine and Professor Nachtsheim, right?

A. Okay. Which one, 00 what?

Q. 242.

A. Okay. All right. I'm there.

Q. And in the middle of the page there in your e-mail you -- you say, "Much better, Paul. You did a good job of hiding the," quote, "agenda," close quote, "and making this look much more impartial. I'll give you an update infection graph and summary tomorrow." Do you see that?



1 ALBRECHT

2 A. Uh-huh.

3 Q. So --

4 A. That seems to line up, I agree.

5 Q. Okay. What was the agenda?

6 A. That's a good question. Generally, in these  
7 presentations you want to have some kind of  
8 strong statement that you're thinking about,  
9 some conclusions, since you've looked through  
10 the data in the past and you've maybe come to  
11 it. So it's -- it's -- after your ability to  
12 deeply study the issue, kind of what your  
13 thoughts on it are, that's generally what the  
14 agenda on it is.

15 Q. And why is making some look more impartial  
16 important?

17 A. Because you want the reader to make their own  
18 determination on this, you don't want to try  
19 and have them go down your direction right  
20 away. You would get a knee-jerk reaction by  
21 doing so.

22 Q. Why would you want to hide your agenda?

23 A. You don't hide it. What you do is make sure  
24 they are aware of all the possible items that  
25 could contribute to it.

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Q. Well, in both -- in Exhibit 29 and Exhibit 28 you talk about hiding the agenda.

A. Yup. You call it an agenda to highlight to the person when you're giving feedback on a presentation like this to be very careful and think though as someone is going to find you that have an agenda, because it helps you as a researcher make sure you've considered all the possible factors.

Q. Okay. Turn to page -- the second page of Exhibit 29, and comment M4 -- well, first of all, read the --

A. Where are we at here?

Q. Second page. Yeah, you're there. The -- what -- the slide that this is apparently commenting on, it simply says, "Intraoperative patient warming significantly improves patient outcomes." And your comment is, "Drop this slide. I'd suggest moving this information down to your ? mark slide, and use a compound sentence to introduce the idea, something like, 'Forced-air warming has many established clinical benefits such as XX and YY. However, the heated airflow presents

1 ALBRECHT

2 a ventilation disruption risk, therefore, we  
3 evaluated.' "

4 And then you go on to say, "As it  
5 stands, this slide," meaning, Intraoperative  
6 Patient Warming Significantly Improves  
7 Patient Outcomes, "is simply stating facts  
8 and not making an argument. To capture  
9 attention an argument must be made" -- "must  
10 be carried forward in every slide, we think  
11 this because X and Y."

12 A. Okay.

13 Q. So you didn't want just neutral facts, you  
14 wanted to make the argument -- you wanted  
15 this presentation to make an argument?

16 A. I would like someone to consider all the  
17 broader topics and then make an argument of  
18 what their interpretation is.

19 Q. To advance the agenda that you're trying to  
20 hide, right?

21 A. Not to hide --

22 MR. ASSAAD: Objection to lack of  
23 foundation, misstates prior testimony.

24 THE WITNESS: Agenda is a keyword  
25 to tag someone's thinking so they make sure

1 ALBRECHT

2 to say, Hey, I don't want to have this come  
3 across like I have an agenda, so what are all  
4 the things so someone can see it. That's how  
5 we talk about that in research, just to make  
6 sure that you presented all the context --

7 MR. COREY GORDON: Okay.

8 THE WITNESS: -- that's what  
9 that's about. And it comes off very strange  
10 in the way it's worded here, but that's the  
11 intent of it.

12 MR. COREY GORDON: Okay.

13 BY MR. COREY GORDON:

14 Q. And if you drop a little bit further down to  
15 the middle of the page, it says, "Our  
16 clinical concern" -- the slide --

17 A. Where are we looking?

18 Q. It would be, I guess, the second from the  
19 bottom up slide.

20 A. Okay.

21 Q. "Our clinical concern was that a potential  
22 for hot-rising air from the forced-air system  
23 to disrupt laminar airflow with possible  
24 consequences for airborne pathogenic  
25 contamination." Did I read that right? I

1 ALBRECHT

2 probably screwed up something.

3 MR. ASSAAD: I wasn't paying  
4 attention.

5 THE WITNESS: I will read it.  
6 "Our clinical concern was that there was a  
7 potential for hot-rising air from the  
8 forced-air system to disrupt laminar airflow  
9 with the possible consequences for airborne  
10 pathogenic contamination."

11 MR. COREY GORDON: Okay.

12 BY MR. COREY GORDON:

13 Q. And then Mike Reed's comment, or MRR6, is,  
14 "I'm attempted to say the driver for this was  
15 the need to verify the smoke DVD produced by  
16 Augustine. Remind them this DVD was posted  
17 to all ortho surgeons in the UK last year,  
18 assuming that is correct."

19 A. Okay.

20 Q. Okay. And you -- you commented, apparently,  
21 in response to that.

22 A. Would you like me to read it?

23 Q. Yeah, what was your comment?

24 A. My comment here in the writing is, "I'd be  
25 careful" --

1 ALBRECHT

2 MR. ASSAAD: Objection; lack of  
3 foundation, assumes that these are his  
4 comments. You may answer.

5 THE WITNESS: Go ahead and read it  
6 for me.

7 BY MR. COREY GORDON:

8 Q. No why don't you read comment M7.

9 A. I'd rather not.

10 Q. Okay. "I'd be careful here. That might  
11 imply a strong corporate agenda behind these  
12 activities and raise questions to the  
13 credibility of the result."

14 A. Yeah.

15 Q. Okay. Now, so Dr. Reed was saying the driver  
16 behind the study was the DVD -- the smoke DVD  
17 produced by Augustine. And you were saying  
18 no, don't -- don't say that, because that  
19 might imply a strong corporate agenda behind  
20 these activities --

21 MR. ASSAAD: Objection; lack --

22 BY MR. COREY GORDON:

23 Q. -- and raise questions as to the credibility  
24 of the results.

25 MR. ASSAAD: Sorry. Objection;

1 ALBRECHT

2 lack of foundation, assumes facts not in  
3 evidence.

4 THE WITNESS: So there is a  
5 comment here, I presume it to be mine.

6 BY MR. COREY GORDON:

7 Q. But the comment you specifically were saying,  
8 "Let's not say that it was the Augustine  
9 smoke DVDs that we were trying to verify."

10 A. That's my opinion here, that I think you get  
11 a knee-jerk reaction from people that don't  
12 consider the whole piece impartially if you  
13 focus it on a company being the motivating  
14 reason.

15 Q. Okay. And when you refer to, "These  
16 activities," and the -- and the, "Credibility  
17 of the results," we're talking about the --  
18 the McGovern paper, Exhibit 8, right?

19 MR. ASSAAD: Objection to form.

20 THE WITNESS: No, we are not.  
21 We're talking about what's in the body of the  
22 presentation.

23 MR. COREY GORDON: Okay.

24 BY MR. COREY GORDON:

25 Q. Well, is -- what was the presentation based

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on other than -- if not the McGovern -- the work you did for the paper that ended up being Exhibit 8, what other work was this based on?

A. Whatever cut of that we're presenting as part of this presentation.

Q. Well, what -- what was -- what were the activities and what were -- what the results that you're presenting?

A. This looks like it's a study based on the airflow disruption component for the presentation.

Q. Did you do any other activities with Reed and McGovern on airflow disruption besides the work that you present in Exhibit 8?

A. I believe we did a study at the University of Minnesota at one point in time.

Q. Was that before or after the work that you did at Northumbria?

A. I'm unsure.

Q. And was that ever published?

A. Yes, we have one of these published papers here. Sorry, it's hard to find through the exhibits what we've got here. (Reviews



1 ALBRECHT

2 document.) So I see this, "Patient Warming  
3 Excess Heat: The Effects on Orthopedic  
4 Operating Room Ventilation Performance, the  
5 NA article.

6 Q. That's Exhibit 7?

7 A. Yup.

8 Q. And that was published in 2013?

9 A. Yup.

10 Q. And when you were preparing this BHS Hip --  
11 the British Hip Society presentation in  
12 February of 2011, was that -- do you think  
13 that might have been talking about the work  
14 you did at University of Minnesota?

15 A. I don't believe so. Unless there's some note  
16 on the bottom, I'm unsure.

17 Q. It was about the stuff you were doing -- you  
18 had done at Northumbria, right?

19 A. This is a long time ago. I'm not sure what's  
20 getting rolled in here and what comments are  
21 a part. I can look through in more detail,  
22 if I'd like.

23 Q. No, let's move on.

24 (Whereupon, Exhibit 30 was  
25 marked for identification.)

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BY MR. COREY GORDON:

Q. I'm going to show you Exhibit 30.

A. Okay.

Q. That's an e-mail from you to Professor David Leaper, right?

A. Okay, in 2010.

Q. And Dr. Leaper's name appears as a coauthor on a couple of your -- your papers, right?

A. He does.

Q. Okay. And in the middle of this you say, "As mentioned, we need you to be the corresponding author." Do you see that sentence?

A. Okay.

Q. What did you mean by, "We need you to be the corresponding author"?

A. He's going to handle the submission details.

Q. And now drop a little further down. You say, "Also, we need to be critically careful that this document appears to be impartial."

A. As with all research.

Q. Well, why were you asking Dr. -- and then you ask Dr. Leaper to, "Please reread and let me know if there is" -- "are any reasons

1 ALBRECHT

2 suggesting that it may appear otherwise."

3 A. That's just checking the quality of your  
4 work. You want your writing, your research,  
5 things like that, to be as impartial as you  
6 can, especially in the work that you present.

7 Q. Well, you didn't say you wanted the document  
8 to be impartial. You said you wanted it to  
9 appear to be impartial, right?

10 A. That's not what I interpret that as, but I do  
11 see what you're saying.

12 Q. Okay. And, you know, we've gone through some  
13 documents now, you talked about hiding  
14 agendas and appearing to be impartial.

15 A. I am not talking about --

16 MR. ASSAAD: There is nothing  
17 about hiding agendas.

18 THE WITNESS: My definition --

19 MR. ASSAAD: Objection to form,  
20 misstates prior testimony, lack of  
21 foundation, assumes facts not in evidence, a  
22 preamble and argumentative.

23 THE WITNESS: On the record, when  
24 we use the word agenda, we do so to talk  
25 about what someone who is looking for

1 ALBRECHT

2 conflicts would think about to highlight that  
3 to someone that, Hey, think about it, you may  
4 have an agenda at play here, because it  
5 highlights their need to think through  
6 carefully and critically about what that  
7 might be.

8 BY MR. COREY GORDON:

9 Q. And in Exhibit 28 you said to Paul McGovern,  
10 "You did a good job of hiding the," quote,  
11 "agenda," close quote, "and making this  
12 document look much more impartial," right?

13 A. Yeah, he did a good job --

14 MR. ASSAAD: Objection; asked and  
15 answered.

16 THE WITNESS: -- of bringing in  
17 surrounding issues that could be a possible  
18 contributor so people get the broad picture  
19 and can make their own conclusion.

20 BY MR. COREY GORDON:

21 Q. Well, if he hadn't hidden the agenda, it  
22 wouldn't have looked quite as impartial,  
23 right?

24 MR. ASSAAD: Objection to form --

25 BY MR. COREY GORDON:

1 ALBRECHT

2 Q. Isn't that what you were saying?

3 MR. ASSAAD: Sorry.

4 THE WITNESS: No.

5 MR. ASSAAD: Sorry to cut you off,  
6 Corey. Objection to form, argumentative,  
7 assumes facts not in evidence, lack of  
8 foundation, assumes facts -- that's it.

9 THE WITNESS: That was slang for  
10 saying you made this look much more impartial  
11 and did a good job bringing in the  
12 surrounding elements that could be relevant.

13 MR. COREY GORDON: Okay.

14 (Whereupon, Exhibit 31 was  
15 marked for identification.)

16 BY MR. COREY GORDON:

17 Q. I'm going to show you Exhibit 31.

18 A. Yeah.

19 Q. This is a -- an e-mail from you to Mike Reed,  
20 Paul McGovern, carbon copies to Scott  
21 Augustine, Andreas Deibel, Keith Leland,  
22 R. Humble, and Christopher Nachtsheim, right?  
23 It's July 9th, 2010, right?

24 A. Okay.

25 Q. And at the time of July 9th, 2010,

1 ALBRECHT

2 Andreas Deibel, Keith Leland, and R. Humble,  
3 in addition to Scott Augustine, were all  
4 employees of Augustine Biomed, right?

5 A. Yeah, Andreas, Keith, this is 2010, yeah,  
6 that would be correct.

7 Q. Who is R. Humble?

8 A. He's a sales rep in Europe.

9 Q. Oh, okay. Do you know if he's still with the  
10 company?

11 A. I don't presume to know.

12 Q. Okay.

13 A. In fact, I'm not ever sure he was directly  
14 employed, he could have been a distributor.

15 Q. And the -- your subject line on your e-mail  
16 is, "Publication factory continues," right?

17 A. Yes, it is.

18 Q. Okay. And you say to Paul and Mike, that  
19 would be Paul McGovern and Mike Reed, right?

20 A. Yeah.

21 Q. And that -- those are the same two people  
22 that you -- in that earlier e-mail that we  
23 looked at today you refer to as "our  
24 researchers," right?

25 A. In the earlier e-mail those are folks that

1 ALBRECHT

2 we've worked with in the past.

3 Q. Yeah. And you refer to them as, "Our  
4 researchers," right?

5 MR. ASSAAD: Objection to form.

6 THE WITNESS: That was not what  
7 was implied by that.

8 BY MR. COREY GORDON:

9 Q. I don't know what -- I'm not asking you what  
10 was implied, I'm asking you how you referred  
11 to them.

12 MR. ASSAAD: Objection to form.

13 THE WITNESS: I'm happy to read  
14 that e-mail. Which exhibit? Which spot? I  
15 know which one you're talking about, but I  
16 want to look at that carefully if you want a  
17 statement like that. (Reviews document.)

18 No, I did not refer to them as, "Our  
19 researchers." "He actually sent this to the  
20 doctors that do our research."

21 BY MR. COREY GORDON:

22 Q. I'm sorry, "The doctors that do our  
23 research."

24 A. So that is a misstatement.

25 Q. Well, thank you for correcting me.

1 ALBRECHT

2 So, "The doctors that do our  
3 research," the Paul -- that's Paul McGovern  
4 and Mike Reed?

5 A. Among others. But, yes, we have definitely  
6 given them paid support to work with them on  
7 research products.

8 Q. And the, "Publication factory that  
9 continues," e-mail, you tell Paul and Mike,  
10 "At this point we have three completed  
11 manuscripts that are ready to be submitted  
12 for publication that you are both authors  
13 on," right?

14 A. Okay.

15 Q. And you list three documents, right?

16 A. I see that.

17 Q. You say, "I've already sent both of you  
18 articles 1 and 2. Article 3 is a new one  
19 and, arguably, the best of the three." Do  
20 you see that?

21 A. Okay.

22 Q. How were -- how is it that you were sending  
23 them an article that was new that they were  
24 coauthors on?

25 A. It was probably a start of a draft as a



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placeholder for us all to work from, it may have been, or it may have had some input or may have been other manuscripts that have been rehashed together to form a more cohesive story.

Q. You were the primary author of -- of these studies, right?

A. Not true. I was the person that did the engineering studies, I'm the person that did a portion of the statistics under oversight from others.

Q. You -- you did the drafting and sent it to other people for review, right?

MR. ASSAAD: Objection to form, asked and answered.

THE WITNESS: No. I would construct parts of these and then we'd work as a team to collaboratively figure it out.

BY MR. COREY GORDON:

Q. Well, so what was -- where was the publication factory?

A. Where was the publication factory?

Q. Yeah.

A. That refers to the fact that we've got three

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articles that we're targeting clinical journals with, and that's a point of pride, that we can produce research at a rate like that.

Q. Okay. Now drop down to the bottom of Exhibit 31 --

A. Okay.

Q. -- where you say, "Also, Dr. Andrew Legg has invited you guys to Sheffield Hospital the weekend of July 17th and 18th to help with the research effort there. If you are interested the company would be willing to cover your hotel and expenses." Do you see that?

A. Yeah.

Q. Do you know, first of all, if either Paul McGovern or Mike Reed took you up on that offer and went to Sheffield and --

A. I'm trying to remember.

Q. -- helped with Dr. Andrew Legg's research effort?

A. I don't recall them being there.

Q. You were there though, right?

A. I was for part of it.

1 ALBRECHT

2 Q. Okay. Anyone else from the Augustine company  
3 there that you can recall?

4 A. No.

5 Q. Who else was there -- who else participated  
6 in the research effort that you're referring  
7 to there?

8 A. Which one? The Sheffield one?

9 Q. Yup.

10 A. That would be myself and Dr. Andrew Legg.

11 And they look the data and they made a  
12 manuscript anova with -- really, without my  
13 involvement and went a separate path.

14 Q. And when you say they took the data, what --  
15 what -- strike that. What --

16 A. We lended [sic] them a study kit to work  
17 with.

18 Q. What do you mean by study kit?

19 A. Equipment.

20 Q. What kind of equipment?

21 A. Airflow measurement devices.

22 Q. So you just -- did you just drop them off or  
23 did you actually participate in doing the  
24 measurements?

25 A. Participated in some.

1 ALBRECHT

2 Q. And you -- but you didn't have anything to do  
3 with any of the drafting of the research?

4 A. I'm trying to remember that one. I believe  
5 that we might have done some drafting, but at  
6 some point they decided that they were going  
7 to write their own. I'm trying to recall the  
8 details on that.

9 (Whereupon, Exhibit 32 was  
10 marked for identification.)

11 BY MR. COREY GORDON:

12 Q. I'll show you Exhibit 32. It's the  
13 document produced from the files of  
14 Professor Nachtsheim.

15 A. Okay.

16 Q. And the cover page is a -- an e-mail from you  
17 to a Dr. Andrew Legg, Scott Augustine and  
18 Christopher Nachtsheim.

19 A. Okay.

20 Q. And the date of this is September 10th, 2010.  
21 That would be after you went to Sheffield and  
22 worked with Dr. Legg, right?

23 A. I believe so.

24 Q. Okay. And the attached manuscript is  
25 entitled, "Forced-Air Warming, Effective, but

1 ALBRECHT

2 Risky? Patient Warming Systems and Their  
3 Effect on Orthopedic Laminar Ventilation,"  
4 right?

5 A. That is what's here.

6 Q. And it lists four authors, Andrew Legg,  
7 Andy Hamer, Mark Albrecht and Christopher  
8 Nachtsheim, right?

9 A. I see that.

10 Q. And you sent this manuscript to Dr. Legg,  
11 Dr. Augustine and Professor Nachtsheim,  
12 right?

13 A. That appears to be correct.

14 Q. You are the one who wrote this first draft,  
15 right?

16 A. Big parts of it, it appears that way, yes.

17 Q. Well --

18 A. Yes.

19 Q. Okay. And why were you sending it to  
20 Scott Augustine?

21 A. Because he's a research sponsor. He is  
22 paying the bill for my salary and others, and  
23 so we do keep him informed with the research  
24 we're doing and the progress we're making. I  
25 am an employee there.

1 ALBRECHT

2 Q. Did -- has anyone ever informed the -- the  
3 public that Dr. Augustine was somehow  
4 involved in the Legg research?

5 A. Dr. Augustine in the Legg research, I don't  
6 know. They did not use this manuscript, by  
7 the way, this one was torpedoed.

8 Q. Who torpedoed it?

9 A. The doctors, Legg and Hamer. They decided  
10 that they wanted a different message and so  
11 they crafted their own.

12 Q. Based on the research that you had helped  
13 them with, right?

14 A. That I don't know.

15 MR. ASSAAD: Objection; calls for  
16 speculation.

17 BY MR. COREY GORDON:

18 Q. Well, do you know if they completely threw  
19 out the research that you went to Sheffield  
20 and worked with them on?

21 MR. ASSAAD: Objection to form.

22 THE WITNESS: Do you have a  
23 publication we can look at to assess that or  
24 do you have any details? It's been a while.

25 BY MR. COREY GORDON:

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Q. I'm just asking you if you have any recollection that, you know, you --

A. I don't without written record to help me with this.

Q. Okay. But you -- you -- you recall going to Sheffield?

A. Yes.

Q. You recall participating in -- in experiments using bubbles, right?

A. I recall helping with a draft and I recall them deciding that we're going to go a different direction.

Q. Okay. But I want to focus on the -- the -- the stuff you did in Sheffield in July of 2010.

A. Okay.

Q. You -- the -- one of the things you were doing was airflow study with bubbles, right?

A. I had lent a research kit and showed how to use it, yeah.

Q. Well, you say you showed how to use it. You actually did it, right? You actually generated -- turned on the bubble generator and worked with them in terms of moving

1 ALBRECHT

2 the --

3 MR. ASSAAD: Objection to form.

4 THE WITNESS: Under the direction  
5 of Dr. Hamer -- actually, not Dr. Hamer,  
6 Dr. Legg, I assisted him.

7 BY MR. COREY GORDON:

8 Q. But you --

9 THE WITNESS: I was physically in  
10 the operating room at times, yes.

11 BY MR. COREY GORDON:

12 Q. And you were assisting him doing the actual  
13 airflow studies, right?

14 A. The studies that were described here, yes.

15 Q. Okay. Let me show you Exhibit 33.

16 (Whereupon, Exhibit 33 was  
17 marked for identification.)

18 BY MR. COREY GORDON:

19 Q. This is from October 4th, 2010, and it's  
20 from you to Andrew Legg, Andrew Hamer,  
21 Thomas Cannon, Scott -- with a cc to  
22 Scott Augustine, Mike Reed, Paul McGovern,  
23 Robert Gauthier and Christopher Nachtsheim,  
24 right?

25 A. That appears correct.



1 ALBRECHT

2 Q. And you said to, "Andrew, Andrew and Thomas,"  
3 and I -- that would be Andrew Legg, Andrew  
4 Hamer and Thomas Cannon, right?

5 A. Yes.

6 Q. You said you, "Wanted to send out a group  
7 e-mail to all of the investigators involved  
8 in the Sheffield study that Andrew Legg was  
9 kind enough to host and supervise. As you  
10 know, we collected some compelling results at  
11 Sheffield related to forced-air warming and  
12 laminar flow disruption that need to be  
13 shared with the orthopedic community at  
14 large. These results are a piece of a larger  
15 body of work which has involved the other  
16 investigators copied on this e-mail.

17 Mr. Mike Reed, Northumbria, Wansbeck;

18 Mr. Paul McGovern, Northumbria, Wansbeck;

19 Dr. Robert Gauthier, Minneapolis, Minnesota;

20 and Dr. Christopher Nachtsheim, University of  
21 Minnesota."

22 And then if you drop down to the  
23 bottom of this paragraph -- well, first of  
24 all, did I read all that right?

25 A. So far.

ALBRECHT

Q. Okay. And at the bottom of this first page you say, "I'll also be sending out a revised manuscript that includes Andrew Legg's comments, suggestions in the next week or two."

A. Uh-huh.

Q. Okay. What manuscript was that?

A. It's possible I was looking for feedback on this one. But, again, like I said, they decided to go a different direction and broke off the relationship.

Q. How did they break off the relationship?

A. They broke off the relationship, as I recall, and, again, it's fuzzy, but I remember Dr. Hamer, who is a senior physician, felt that they would like to have their own independent ability to work with these results without any kind of influence from our research group, is essentially what it came down to, and they wanted to have their own message and crafted in their own way.

Q. Based on the --

A. That I don't know.

Q. -- experiments that you assisted in, correct?

1 ALBRECHT

2 A. As far as I can tell, yes, that's the data  
3 that they used when they broke off the  
4 relationship.

5 Q. Okay. And -- well, what was the time period  
6 when they broke off the relationship?

7 A. Obviously, it would be after this, because we  
8 kind of did some back and forth. I believe  
9 we had a couple of phone calls and then it  
10 was decided that we're going to go different  
11 ways.

12 Q. And did you -- are you saying you had no  
13 further contact with him at that point?

14 A. Nothing material, I don't believe. It's hard  
15 to say without written record. They may have  
16 presented us with the draft when it was done,  
17 but they went about it their way.

18 Q. And who did they communicate with to indicate  
19 that they were breaking off the relationship?

20 MR. ASSAAD: Objection to form.

21 THE WITNESS: I do not recall. I  
22 believe it was with myself and the research  
23 group. I don't remember if it was via e-mail  
24 or telephone call. I'm trying to recall.  
25 They may better remember that when you talk

1 ALBRECHT

2 to them.

3 BY MR. COREY GORDON:

4 Q. Did you discuss with Scott Augustine that  
5 they were breaking off the relationship?

6 A. Oh, yes.

7 Q. Well, what do you recall that discussion  
8 entailing?

9 MR. ASSAAD: Objection; lack of  
10 foundation.

11 THE WITNESS: I would need some  
12 written record to help jog my memory on that.  
13 If you have something, I'd be appreciative.

14 (Whereupon, Exhibit 34 and  
15 Exhibit 35 was marked for  
16 identification.)

17 BY MR. COREY GORDON:

18 Q. I'm going to show you Exhibits 34 and 35.

19 A. Okay.

20 MR. ASSAAD: Which one is 34 and  
21 which one is 35?

22 MR. COREY GORDON: Thirty-four is  
23 the e-mail, 35 is the article.

24 BY MR. COREY GORDON:

25 Q. Exhibit 34 is an e-mail from you to

1 ALBRECHT

2 Keith Leland dated October 25th, 2012,  
3 correct?

4 A. Yes.

5 Q. And in it you hyperlink to an article in the  
6 Star Tribune, and Exhibit 35 is that article,  
7 correct?

8 A. I'm assuming it is. It looks like the links  
9 match.

10 Q. Okay.

11 A. Actually, no, they don't, but I don't know.  
12 I couldn't tell you.

13 Q. Okay. Well, I'll represent to you that on  
14 November 10th, 2016, at 4:19, I put that  
15 hyperlink from your e-mail, Exhibit 34, into  
16 my browser, and that -- what came up was  
17 Exhibit 35.

18 A. Yeah.

19 Q. And Exhibit 34 refers to a Medtronic article,  
20 right?

21 MR. ASSAAD: Objection. Objection  
22 to form, assumes facts not in evidence, lack  
23 of foundation that this article is the same  
24 as what's being referenced here in the  
25 e-mail.

ALBRECHT

BY MR. COREY GORDON:

Q. Exhibit 34 refers to a Medtronic article, right?

A. It appears to.

Q. And Exhibit 35 is an article about Medtronic, right?

A. Yes, that you provided me with, yes.

Q. Okay. And the article is about Medtronics' role in influencing articles authored by physician consultants where that role was not disclosed, right?

A. I don't know, I'd have to read it. Hold tight. (Reviews document.) I'm done reading the article.

Q. Okay. And in your e-mail to Keith Leland -- and at this time Keith Leland was also an ex-Augustine employee; is that correct?

A. Yeah, it appears that way.

Q. And you say, "Ha, the Medtronic article sounds scarily familiar. Hum, we were never part of a company that did that," dot, dot, dot, right?

A. Yup, those are the words.

Q. What about the article was scarily familiar?

1 ALBRECHT

2 MR. ASSAAD: Objection; lack of  
3 foundation, assumes facts not in evidence.

4 THE WITNESS: That there's company  
5 funding involved in research.

6 BY MR. COREY GORDON:

7 Q. An undisclosed influence, right?

8 A. No, we always disclosed our influences.

9 Q. Always?

10 A. I have in anything I've submitted.

11 Q. Okay. So what was scary, or scarily  
12 familiar, to use your exact words?

13 A. It's not scary. It's that funding comes from  
14 device companies at times.

15 Q. You used the word scarily. What was scarily  
16 about -- about companies funding research?

17 MR. ASSAAD: Objection to form,  
18 assumes facts not in evidence, lack of  
19 foundation.

20 THE WITNESS: It sounds familiar.  
21 I mean, I -- scarily is just an adjective. I  
22 don't know what to tell you what it means  
23 there.

24 MS. ZIMMERMAN: Can you tell us  
25 how much time we have left?

1 ALBRECHT

2 THE VIDEOGRAPHER: So both  
3 volumes, we're at 6:53 on record.

4 MS. ZIMMERMAN: Thanks.

5 (Whereupon, Exhibit 36 was  
6 marked for identification.)

7 BY MR. COREY GORDON:

8 Q. I'm going to show you Exhibit 36. It's an  
9 exchange of e-mails between you and  
10 Professor Nachtsheim, correct?

11 A. Okay. Yes, it is.

12 Q. Okay. And I want to direct your attention to  
13 the second page where Professor Nachtsheim  
14 says to you, "Hard to disagree with the last  
15 quote where the guys said that the data are  
16 compelling, but they don't prove the link to  
17 infections in practice and a clinical trial  
18 would be needed to do that, do you agree,"  
19 question mark. Did I read that correctly?

20 A. I will read it just to make sure.

21 "Interesting article. Even though they were  
22 petty hard on Scott, hard to disagree with  
23 the last quote where the guy said that the  
24 data are compelling, but they don't provide  
25 the link to infections in practice and that



ALBRECHT

clinical trial would be needed to do that; do you agree?"

Q. You said, "Provide." I think it says, "Prove."

A. My apologies.

Q. And your response was, "Yes, I do agree with that." And, in fact, why don't you read your response.

A. Okay. "Yeah, I do agree with that. Personally, I don't think it's a good idea to use forced-air warming in implant cases sensitive to airborne contamination based off" -- "based upon its effects on clean airflow occurrence over the surgical site, but we do not have conclusive proof at this time that increased infections are the result of such ventilation disruption, nor are we likely to ever have such proof. Such a trial would involve upwards of thousands of patients and carry a \$2 million price tag, at minimum cost of 2,000 a patient I'm guessing. This is one of those things where we can step close to the line, and we do have important information to present that clinicians should

1 ALBRECHT

2 be aware of, but we also have to be careful  
3 that we do not state claims regarding proof  
4 of infection reduction. Unfortunately, Scott  
5 likes to say that he's convinced of such a  
6 relationship, even though I tell him it is  
7 unsupported and I do not agree. Well, that  
8 is the difference between research and  
9 marketing. However, he knows better than to  
10 make such statements in journal articles and  
11 does not pressure me/us to do so. As such, I  
12 figure he can do as he pleases without harm  
13 as long as he respects the research  
14 boundaries, which he has to date."

15 MR. COREY GORDON: Okay. Here's  
16 the deal. I have probably about two hours  
17 more of questioning for you. I know I'm  
18 bumping up to the seven-hour limit. I -- I  
19 would ask you to let me go ahead and finish  
20 up. If you want to say no, you know, absent  
21 special provisions from the court, it's a  
22 maximum of seven hours, that -- that is your  
23 privilege, and I will -- I will likely ask  
24 the -- the court to give some -- give me some  
25 additional time. They're going to have

1 ALBRECHT

2 questions for you and, you know, I'm sure  
3 they don't want me to go on any further.

4 So, you know, I'm going to -- it's  
5 probably partially up to you. But even if  
6 you say, yeah, why don't you just go ahead  
7 and finish with me, they're probably going to  
8 object.

9 MR. ASSAAD: We --

10 MS. ZIMMERMAN: Should we go off  
11 the record for a minute?

12 MR. ASSAAD: Yeah, let's go off  
13 the record.

14 THE VIDEOGRAPHER: We're going off  
15 the record at 11:26 a.m.

16 (Whereupon, a brief recess  
17 was taken.)

18 THE VIDEOGRAPHER: We're going  
19 back on the record at 11:31 a.m.

20 MR. ASSAAD: It's my understanding  
21 that the seven hours are up at this time,  
22 give or take a couple of minutes. I don't  
23 know if Mr. Gordon has any questions.

24 We definitely want to ask -- we  
25 definitely object to defense counsel moving

1 ALBRECHT

2 forward over the seven-hour time limit that's  
3 been allowed to him by the Federal Rules of  
4 Civil Procedure.

5 However, I will likely go to the  
6 court and ask for a couple of hours for me to  
7 follow up on some of the questions he had  
8 with the -- with the -- with the objection  
9 that they have no more time with regard to  
10 the deposition. Seven hours has been ample  
11 time. You can only -- you know, in your role  
12 with 3M and Arizant does not allot for more  
13 than a seven-hour deposition.

14 Therefore, I think we'll close this  
15 deposition for now and then we'll come back  
16 at a later time after court's guidance and  
17 figure out, you know, what the court is going  
18 to allow us to do with regards -- with  
19 regards to the plaintiffs asking questions  
20 and with respect to the defendants asking  
21 questions.

22 MR. COREY GORDON: I understood  
23 Mr. Albrecht was saying that he wanted to --  
24 wanted me to abide by the seven-hour cutoff.  
25 I don't know if he's willing to stay if you

1 ALBRECHT

2 have another hour or two of examination.

3 THE WITNESS: I'm -- I'm going to  
4 abide by the seven-hour cutoff.

5 MR. COREY GORDON: Okay.

6 THE WITNESS: So that is my  
7 choice, yes.

8 MR. ASSAAD: Okay.

9 THE WITNESS: And this is my  
10 Exhibit 30 to add to the pile, right? It's  
11 got a flag on it. Just so we keep them all  
12 together.

13 MR. ASSAAD: We can close, I'll  
14 ask you off the record.

15 THE VIDEOGRAPHER: We're going off  
16 the record at 11:32 a.m.

17 (Whereupon, the foregoing  
18 deposition adjourned at 11:32 a.m.)  
19  
20  
21  
22  
23  
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## DEPOSITION CORRECTION SHEET

TITLE: In Re: Bair Hugger Forced Air Warming  
Products Liability Litigation

WITNESS: Mark Albrecht

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2  
3 I, Mark Albrecht, have read this  
4 deposition transcript and acknowledge  
5 herein its accuracy except as noted:  
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7 \_\_\_\_\_  
8 Witness Signature  
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1 STATE OF MINNESOTA )  
 ) ss  
2 COUNTY OF ANOKA )  
3

4 Be it known that I took the foregoing  
deposition of Mark Albrecht, Volume 2, on  
November 12th, 2016, in Minneapolis, Minnesota;  
5

6 That I was then and there a notary public  
in and for the County of Anoka, State of Minnesota,  
and that by virtue thereof, I was duly authorized  
7 to administer an oath;

8 That the witness was by me first duly  
sworn to testify to the truth, the whole truth and  
9 nothing but the truth relative to said cause;

10 That the foregoing transcript is a true  
and correct transcript of my stenographic notes in  
11 said matter;

12 That the witness reserved the right to  
read and sign the transcript;  
13

14 That I am not related to any of the  
parties hereto, nor interested in the outcome of  
the action;  
15

16 WITNESS MY HAND AND SEAL this 23rd day of  
November, 2016.  
17  
18

\_\_\_\_\_  
Amy L. Larson, RPR  
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